median

eyonis™ LCS

Potentially disruptive Class II medical device for lung cancer screening (LCS)

eyonis™ LCS pivotal REALITY data

What leading U.S. clinical experts are saying

PROF. ANIL VACHANI, MD,
HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

PROF. JAVIER ZULUETA, MD,
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

FREDRIK BRAG,
CEO OF MEDIAN TECHNOLOGIES

ALMDT
EURONEXT
GROWTH

Software as a Medical Device (SaMD)

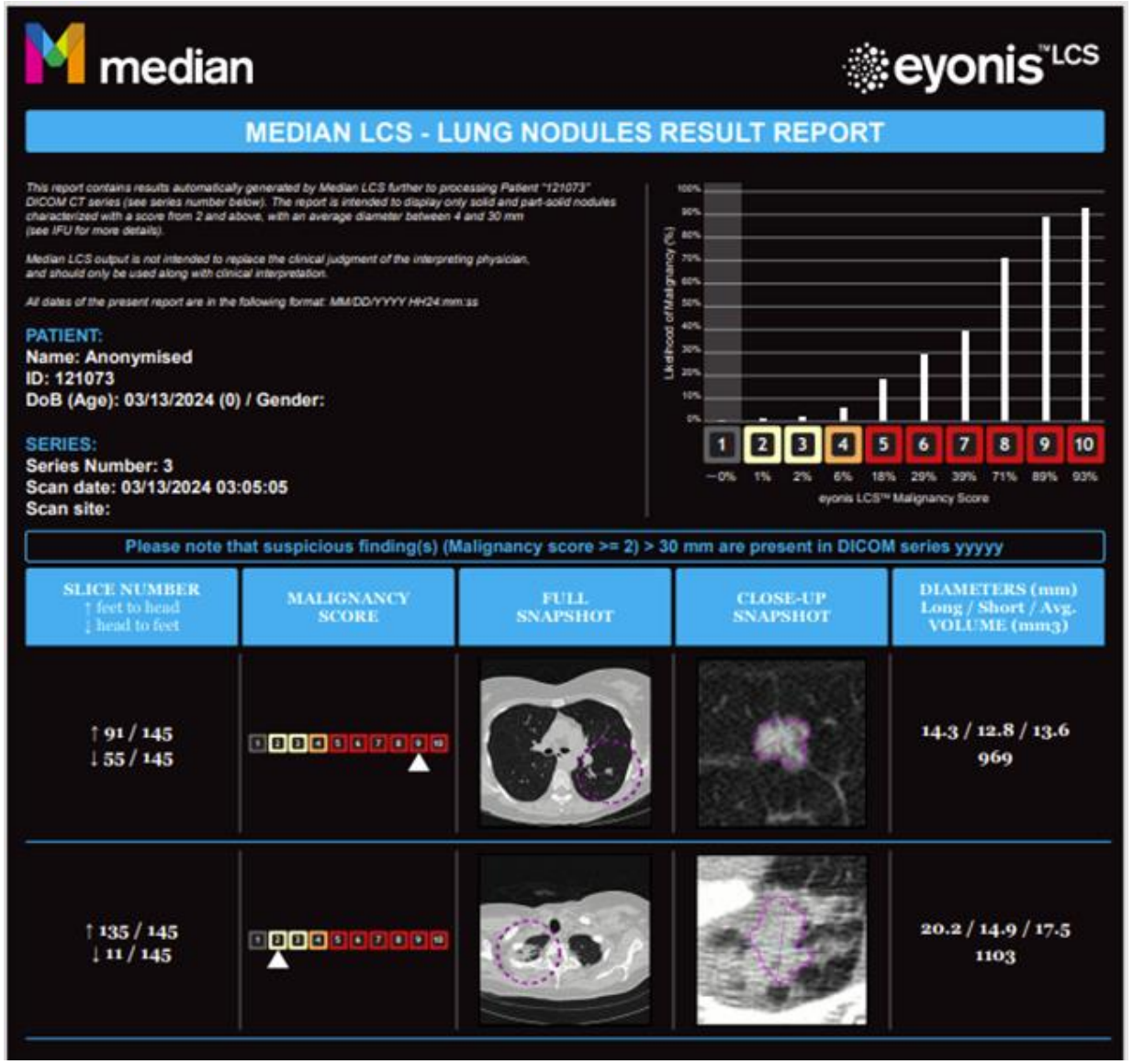
eyonis™ LCS is an AI/ ML tech-based SaMD candidate developed to improve diagnostic accuracy & efficiency of lung cancer screening (LCS)

LCS w/ LDCT alone is a tedious program leading to radiologists' stress & fatigue, hampering its implementation:

- Only 1 in 35 nodules examined is cancerous in average
- Early (Stage 1) lung cancers can be cured in 80-90% of patients but are often near the limit of detection with current methods
- Confirming cancer requires invasive biopsy procedures, which should not be performed unnecessarily
- Yet later stage lung cancers are associated with high mortality necessitating a more aggressive diagnostic approach

eyonis™ LCS could increase accuracy & efficiency even for challenging stage 1 cases at the limit of detection & characterization

eyonis™ LCS could empower healthcare professionals to implement lung cancer screening at scale while improving diagnostic accuracy, helping saving lives, reducing unnecessary invasive tests & preventing expensive best supportive care.



eyonis™ LCS has achieved continuous success, supporting regulatory submissions in H1 2025

Design Phase - **AI Model Research, Definition, Train/Tune/Test**

Verification - **Independent Verification**

Performance Validation - **Standalone Validation**

Clinical Validation - **Multi Reader Multi Case**

Regulatory Submissio & Clearance - **Review FDA / CE Mark**

2022 - 2023

CADe

CADx

Suspicious Malignant

CADe/x

Suspicious Malignant

TRAIN & TUNE

Based on a cohort of 8,709 patients (620 cancer) (LIDC: 1,010+ NLST: 7,699)

May 2024

Manufacturer Values (MV) test

Performed to determine eyonis™ LCS performance

Sensitivity 93.3 %
Specificity 92.4 %
AUC=0.977
All cancer stages, at patient level

Based on a cohort of 2,163 patients (NLST +LIDC/IDRI data)

June 2024

Independent Verification (IV) Study

Performed to verify eyonis™ LCS performance on an independent patient cohort

Sensitivity 93.4 %
Specificity 87.4 %
AUC= 0.949
All cancer stages, at patient level

Based on an independent cohort of 273 patients (91 Cancers / 182 Benign)

Aug 2024

REALITY, 1st pivotal study

Performed to validate eyonis™ LCS standalone performance to diagnose cancer compared to ground truth

AUC= 0.903
All 10 primary & secondary endpoints met
All cancer stages, at patient level

*Based on an **ENRICHED** cohort of 1,147 patients (342 Cancers / 805 Benign)*

Q1, 2025

WE ARE HERE

RELIVE, 2nd pivotal study, MRMC

Performed to demonstrate that eyonis™ LCS increases clinician performance in analyzing LDCT LCS images

ON GOING STUDY, DATA READOUT EXPECTED IN Q1 2025

Understanding sensitivity, specificity & AUC

- Diagnostic **accuracy** is determined by balancing between sensitivity (true positives) and specificity (false positives).

- To rigorously confirm accuracy of diagnostic devices under different conditions, a statistical method, known as the receiver operating characteristic (ROC) curve, is widely used to plot a device's sensitivity against its specificity and calculate the **area under the curve** (AUC).

- **AUC is widely accepted as a measure of accuracy**
  - For reference, a diagnostic test with low accuracy would have an AUC of 0.5 while a perfect test would have an AUC of 1.
  - AUC can be used to compare
    - Different types of diagnostic tests – like liquid biopsies
    - Competing SaMDs tested on similar (or the same) data sets
    - **Performance of the same SaMD on different types of data sets**, which is the focus herein for eyonis™ LCS

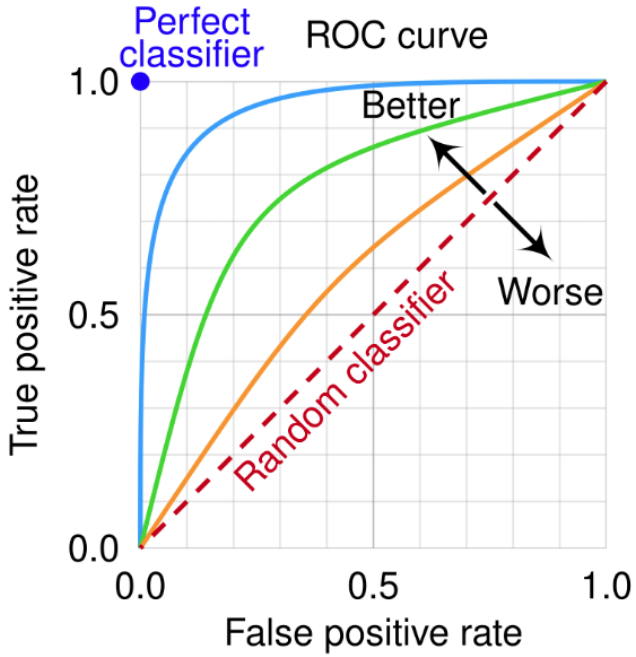


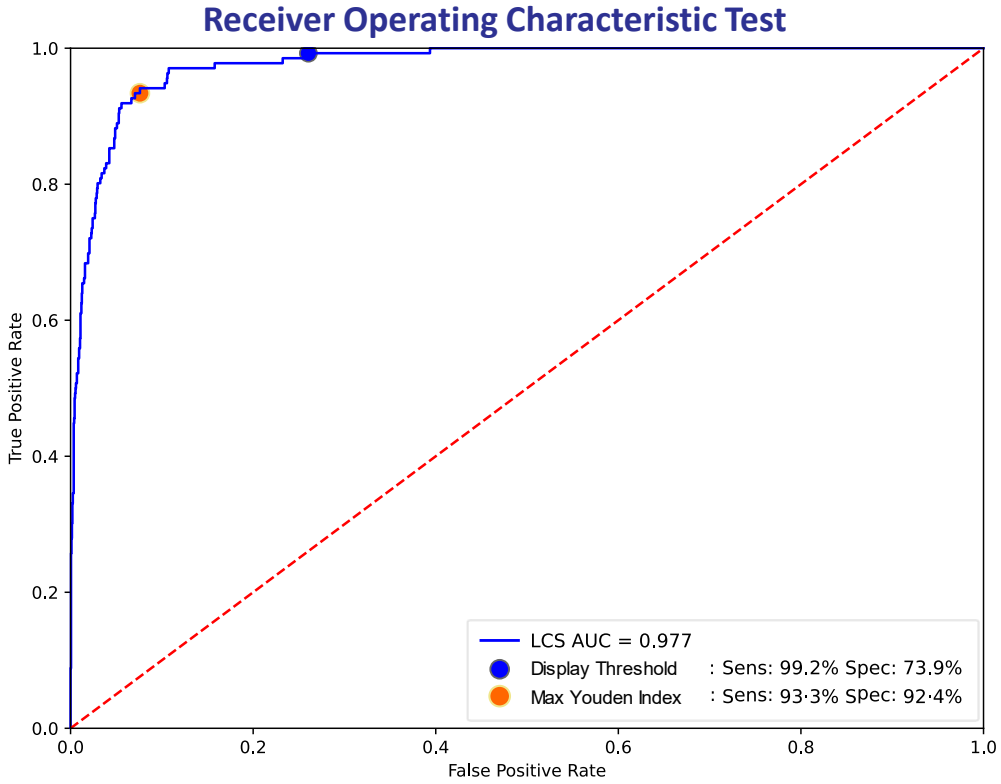
Table 4. Interpretation of the Area Under the Curve

Area under the curve (AUC)	Interpretation
0.9 ≤ AUC	Excellent
0.8 ≤ AUC < 0.9	Good
0.7 ≤ AUC < 0.8	Fair
0.6 ≤ AUC < 0.7	Poor
0.5 ≤ AUC < 0.6	Fail

For a diagnostic test to be meaningful, the AUC must be greater than 0.5. Generally, an AUC ≥ 0.8 is considered acceptable.

eyonis™ LCS Manufacturer Values - May 2024

End-to-end Lung Nodule Detection & Characterization with Outstanding Performance



	NLST test pop 1
Population	B=2027 / C=136

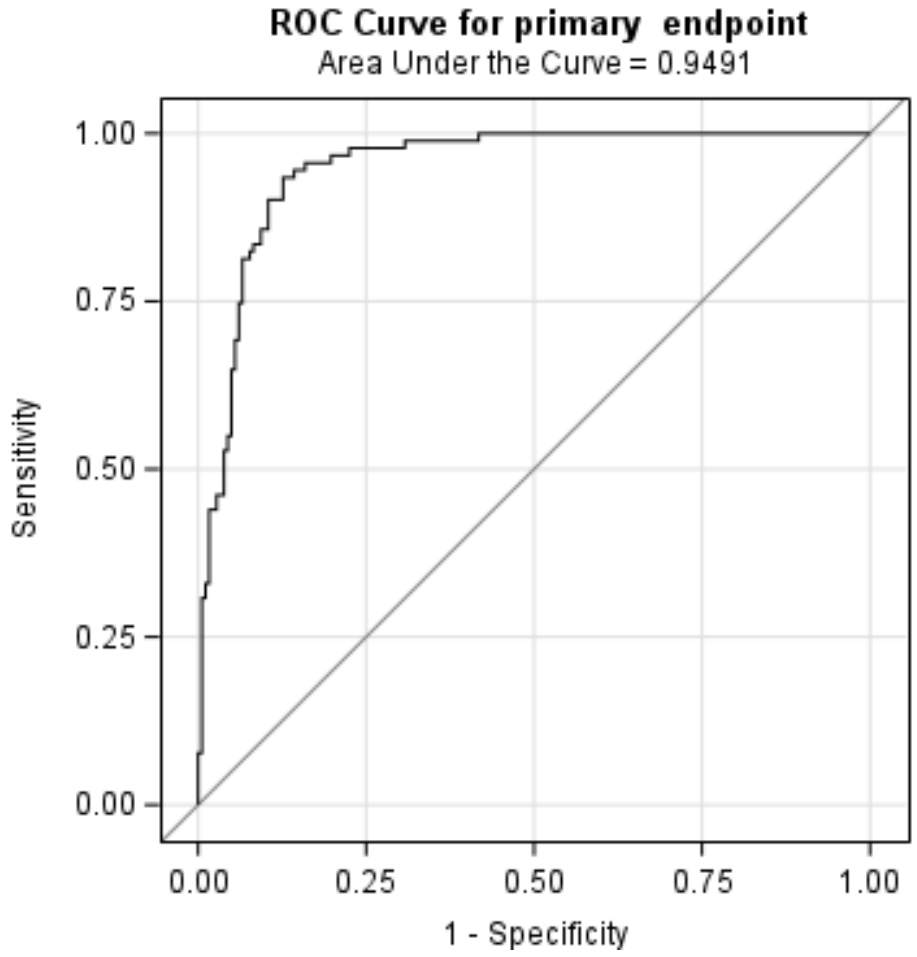
2,163 US patients
136 Cancers / 2,027 Benign

AUC = 0.977

	Sensitivity	Specificity
Cancer / Non-Cancer Characterization (Max Youden Index)	93.3%	92.4%
Suspicious nodules Detection (Display Treshold)	99.2%	73.9%

eyonis™LCS Independent Verification study results - June 2024

Extremely high AUC



273 US / EU patients
91 Cancers / 182 Benign

AUC = 0.949

	Sensitivity	Specificity
Cancer / non-cancer Characterization (Max Youden Index)	93.4%	87.4%
Suspicious nodules Detection (Display Treshold)	98.9%	62.1%

REALITY study at glance

Cohort & Data Sources:

1,147 cases

342 cancerous &

805 non-cancerous

Ratio 1: 2.35 (x10 vs. real life)

Multinational multicentric study

USA: 811 (70.7%)

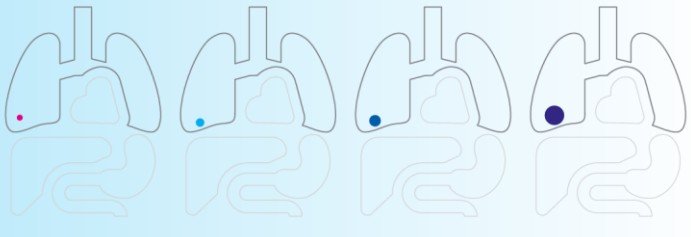
EU: 336 (29.3%)

- Baptist Memphis: 251(21.9%)
- FJD: 180 (15.7%)
- Gradient: 91 (7.9%)
- MD Anderson: 151 (13.2%)
- Navarra: 156 (13.60%)
- UPENN: 227 (19.79%)
- VEGA: 91 (7.93%)

Enrichment

- *Enriched with **more cancer cases** than real life - **30% vs. 3%***
- *Enriched with difficult-to-diagnose cases to stress test device's detection & characterization limits i.e. **small non-spiculated cancerous nodules & early cancer stages***

Cancer staging*



STAGE 1	STAGE 2	STAGE 3	STAGE 4
219 (79.7%)	13 (4.7%)	24 (8,7%)	19 (6,9%)

* 67 cancer staging missing

Nodule characteristics

371 cancerous nodules

Non spiculated 120 (32.3%)

Spiculated 251 (67.7%)

Part-solid 57 (15.4%)

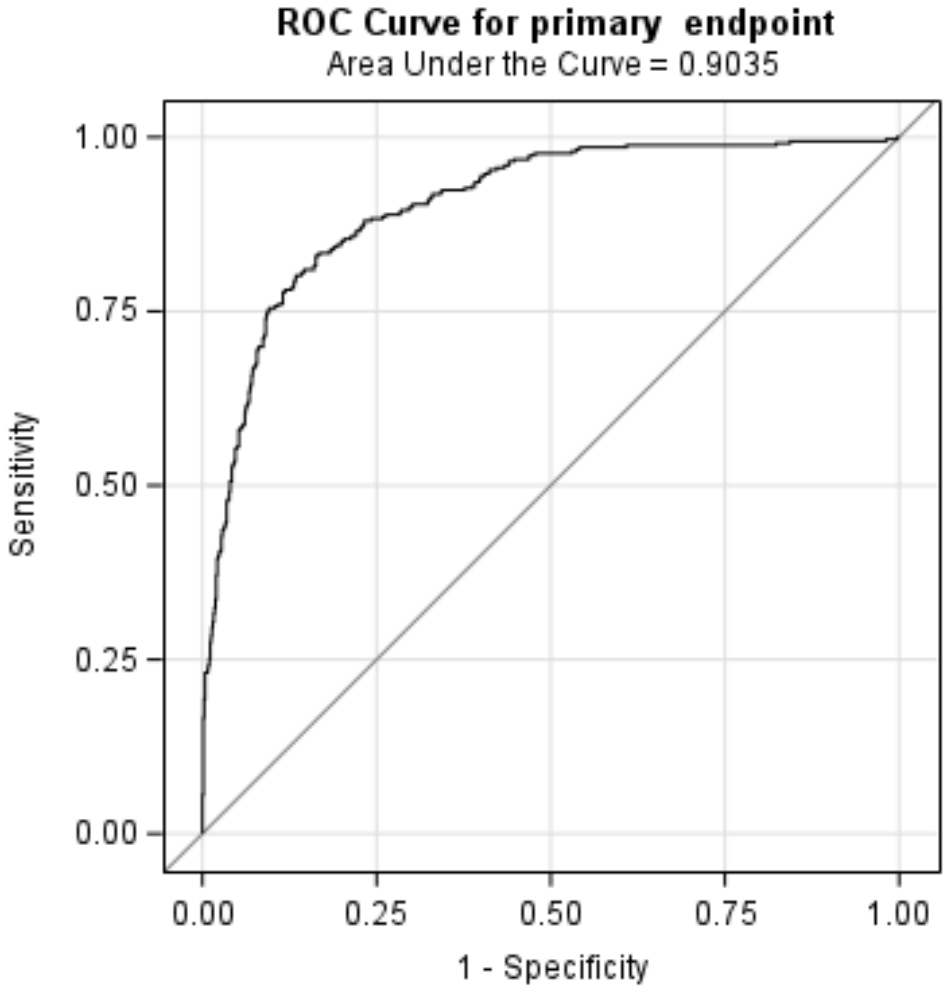
Solid 314 (84.6%)

Size 4-10 mm=70 (20.5%) malignant

Highly enriched population

REALITY study results – primary endpoint

High performance for detection & characterization of cancerous nodules in challenging population (highly enriched population) - primary endpoint met with excellent AUC



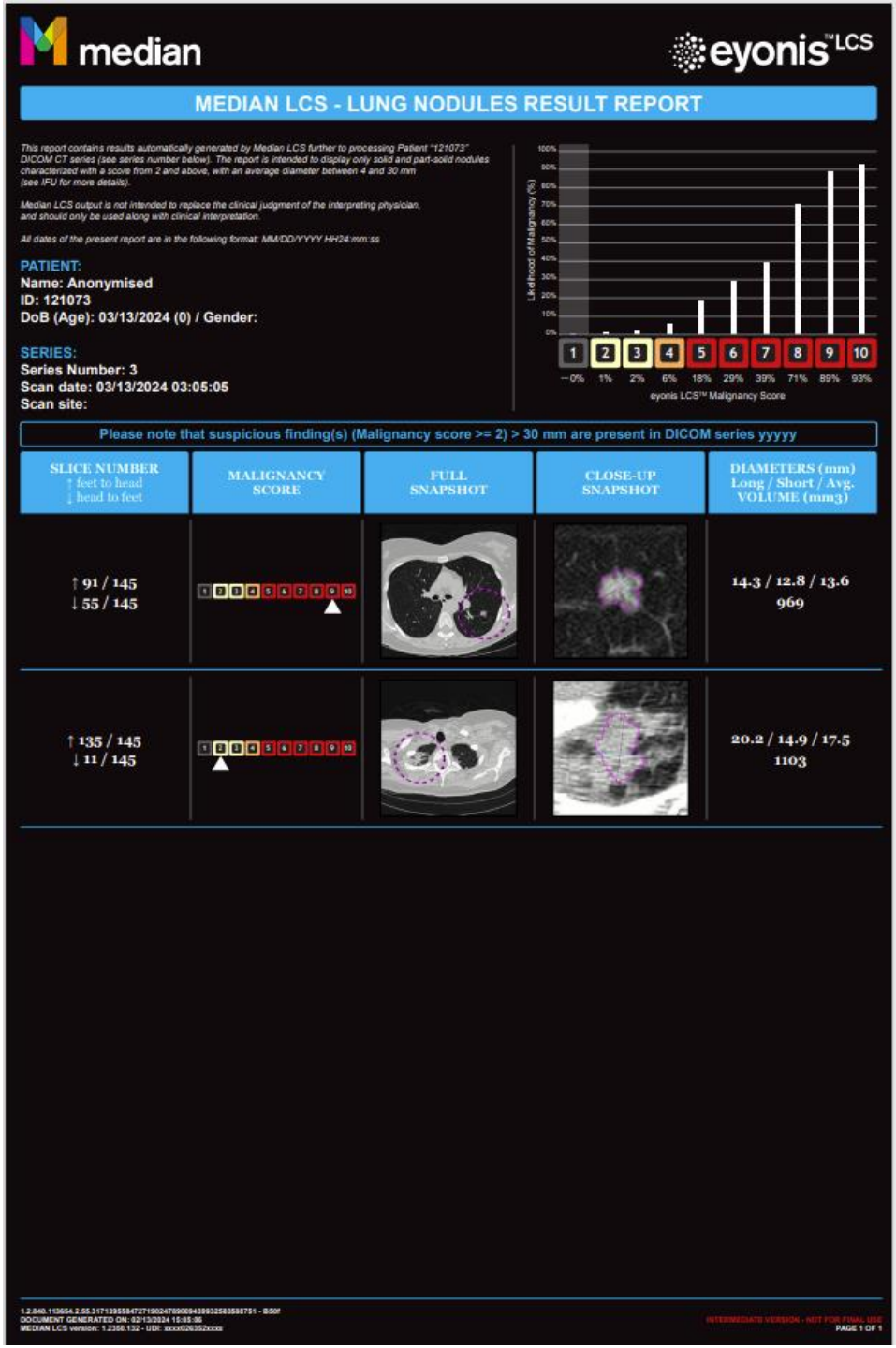
1147 US / EU patients
343 Cancers / 805 Benign

AUC = 0.903

	Sensitivity	Specificity
Cancer / non-cancer Characterization (Max Youden Index)	80.1%	86.6%
Suspicious nodules Detection (Display Treshold)	97.7%	51.2%

REALITY study - all 10 objectives passed

Objective	Criteria	Results	Report features
Primary	**H1: AUC of ROC (patient level) > 0.8**	**Statistically significant (P < 0.0001)**	**Malignancy Score**
Secondary	H2: Sensitivity > 70% when Specificity=70%	**Statistically significant (P < 0.0001)**	Malignancy Score
Secondary	H3: Specificity > 70% when Sensitivity=70%	**Statistically significant (P < 0.0001)**	Malignancy Score
Secondary	H4: AUC of LROC > 0.75	**Statistically significant (P < 0.0001)**	Slice number “feet to head” & “head to feet” to ensure maximum compatibility with all viewers
Secondary	H5: Detection sensitivity>0.8 with average FP rate per scan<1	**Statistically significant (P < 0.0001)**	Full Snapshots – Close-up snapshot
Secondary	H6: ICC>0.8 for average diameter	**Statistically significant (P < 0.05)**	Dimensional information (LA Diameter mm, volume mm3)
Secondary	H7: ICC>0.8 for long axis diameter	**Statistically significant (P < 0.05)**	Dimensional information (LA Diameter mm, volume mm3)
Secondary	H8: ICC>0.8 for short axis diameter	**Statistically significant (P < 0.05)**	Dimensional information (LA Diameter mm, volume mm3)
Secondary	H9: ICC>0.75 for Volume	**Statistically significant (P < 0.05)**	Dimensional information (LA Diameter mm, volume mm3)
Secondary	H10: Dice coefficient > 0.7	**Statistically significant (P < 0.0001)**	Dimensional information (LA Diameter mm, volume mm3)



KOL Discussion

Prof. Anil Vachani, MD, Hospital of the University of Pennsylvania

Prof. Javier Zulueta, MD, Icahn School of Medicine at Mount Sinai

Fredrik Brag, CEO of Median Technologies

REALITY cohort description - nodule size distribution

High ratio of small cancerous nodules & low ratio of big cancerous nodules

Nodules sizes	Cancerous (n=342)	Non cancerous (n=805)
# of cases with nodule size of [4-10 mm[(or without nodule for b)	70 (20.5%)	680 (84.5%)
# of cases with nodule size of [10-20 mm[	203 (59.3%)	111 (13.8%)
# of cases with nodule size of [20-30 mm]	69 (20.2%)	14 (1.7%)

REALITY vs. Independent Verification - nodule size distribution

15% more patients w/ small cancerous nodules & 12% less patients w/ big cancerous

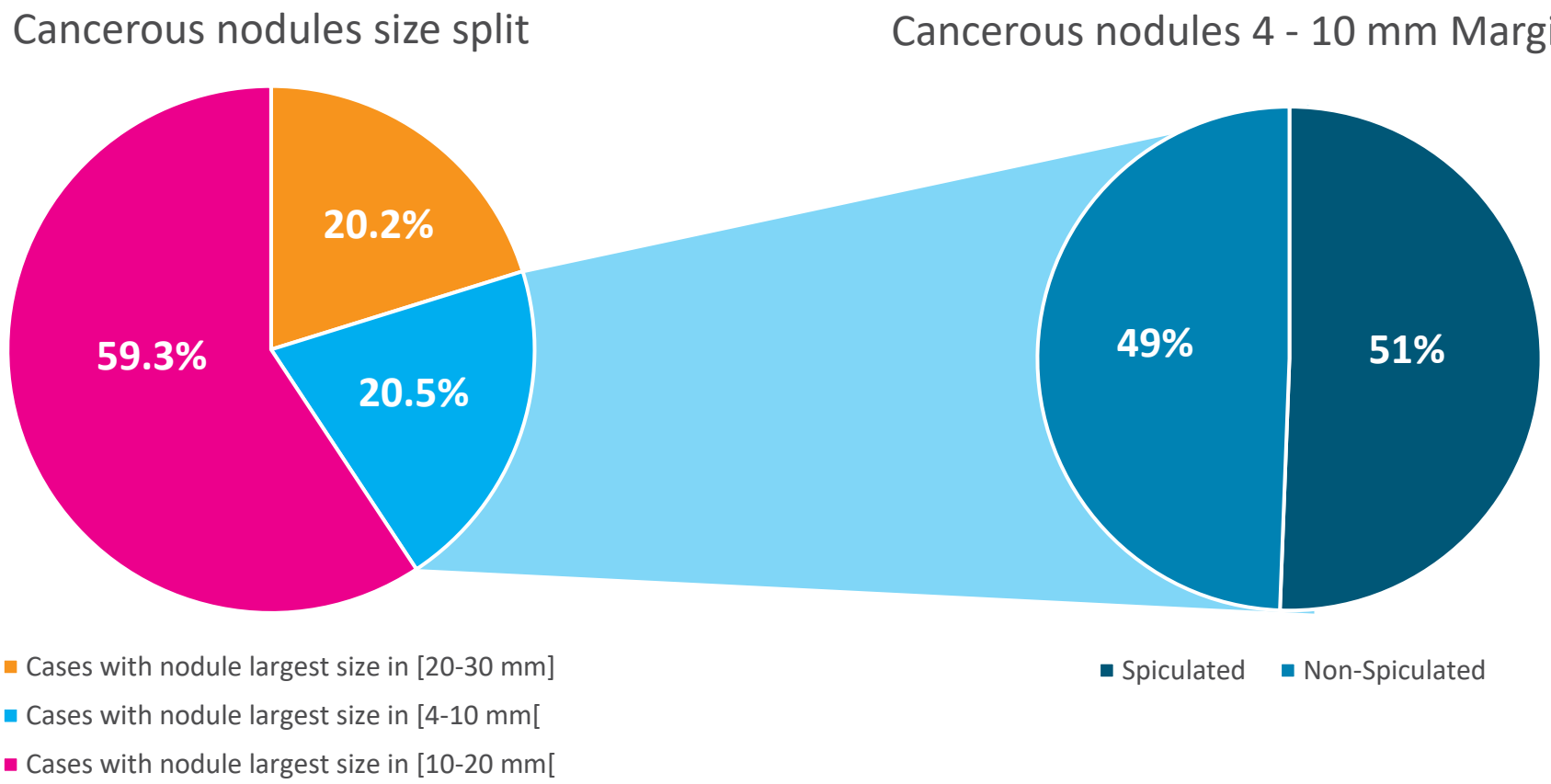
Nodules sizes	Cancerous in Standalone (n=342)	Cancerous in IV (n=72)
# of cases with nodule size of [4- 10 mm[	70 (20.5%)	5 (5.5%)
# of cases with nodule size of [10-20 mm[	203 (59.3%)	57 (62.6%)
# of cases with nodule size of [20-30 mm]	69 (20.2%)	29 (31.9%)

() % from standalone study

() % from Independent Verification study

Focus on small cancerous nodules

High ratio of small cancerous nodules (20.5%) and among them, almost half (49%) are non spiculated



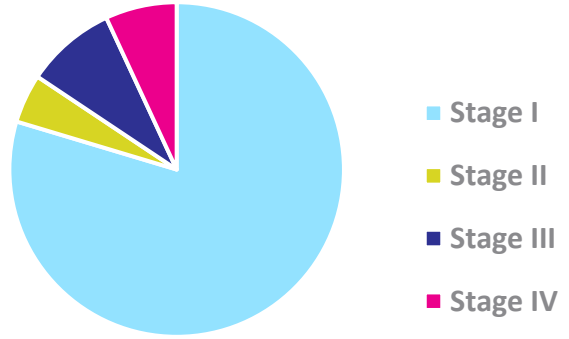
REALITY cohort description - cancer stages

80% stage I within REALITY – very enriched, far above NLST (63%)

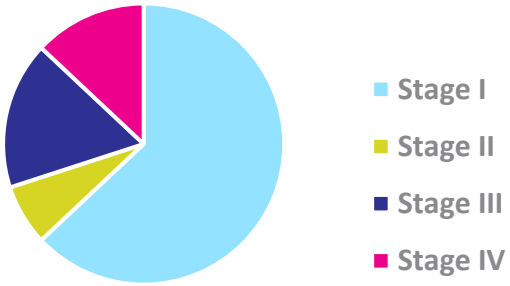
Cancer Stage	REALITY Cohort Cancerous cases	NLST Population Cancerous cases
Stage I	219 (79.7%)	63%
Stage II	13 (4.7%)	7%
Stage III	24 (8.7%)	17%
Stage IV	19 (6.9%)	13%
Total confirmed stage *	275 (100%)	100%

*67 (19.5%) cancer stage was missing from patients' history forms

Cancer stage – REALITY cohort

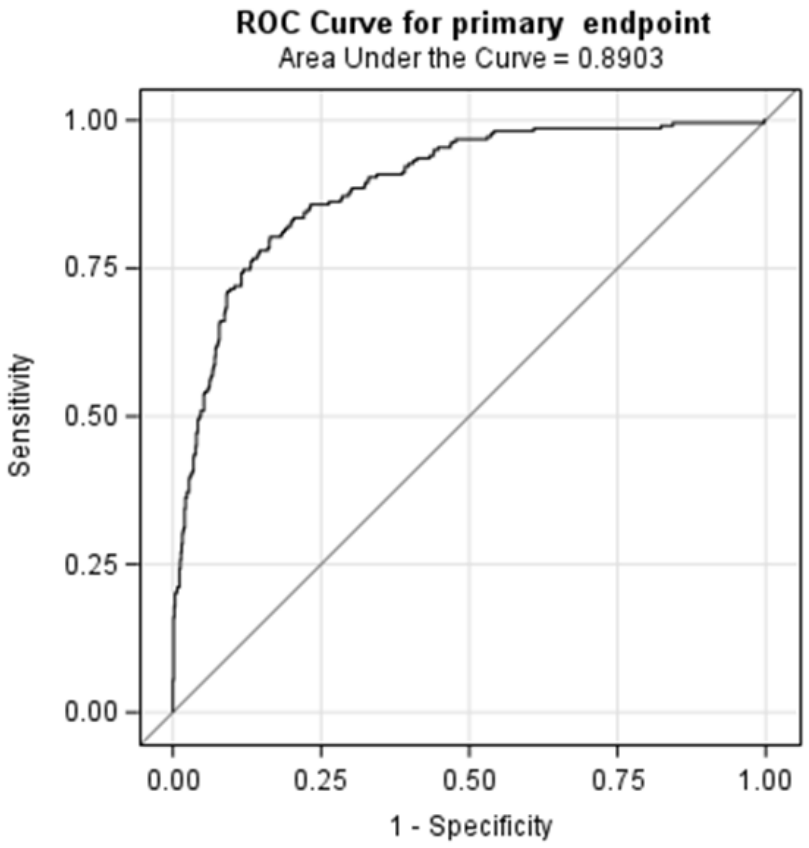


Cancer stage – NLST population



REALITY study exploratory analysis - Cancer Stage I

Very good AUC of 0.890 (almost excellent)



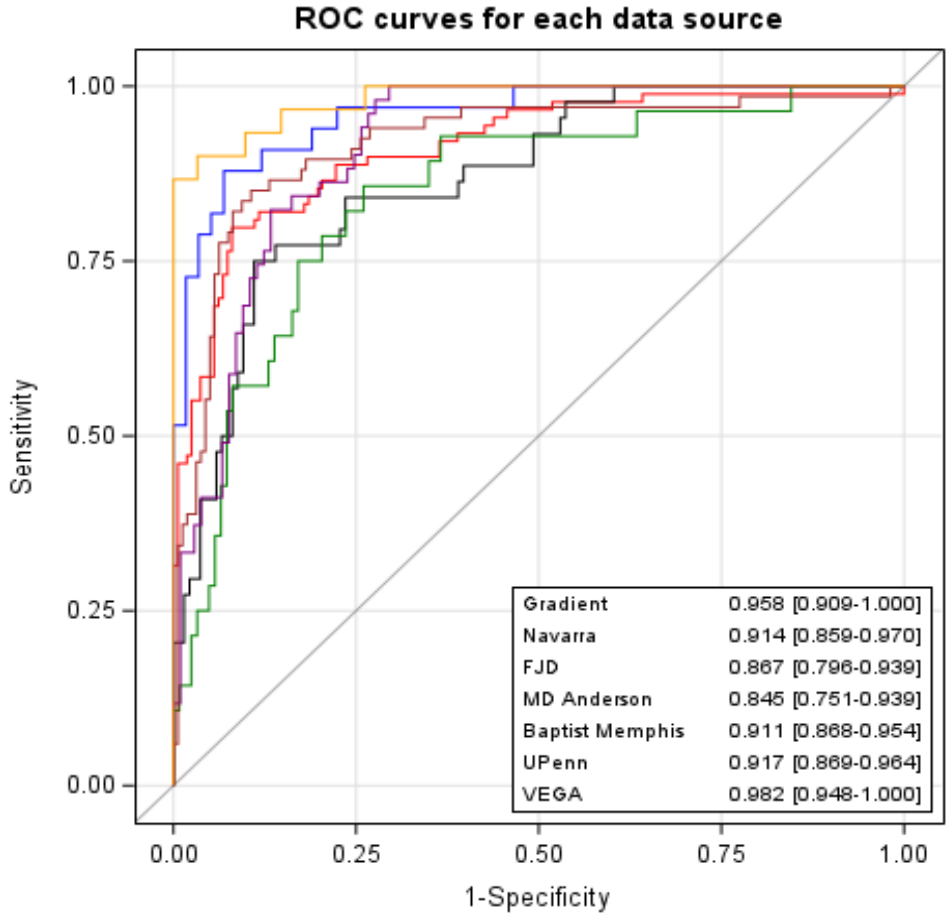
AUC = 0.89

N= 219 patients/cases	sensitivity	specificity
Cancer / non-cancer Characterization (Max Youden Index)	80.4% (176 cases)	83.6%
Suspicious nodules Detection (Display Treshold)	96.8% (212 cases)	51.2%

+36 cases (16.4%) with a suspicious nodule detected which will be more closely followed up

REALITY study exploratory analysis - centers

Different AUCs according to centers with spread from 0.845 to 0.982



AUC > 0.95

- Gradient
- VEGA

AUC>0.90 and <0.95

- Navarra
- Baptist Memphis
- UPenn

AUC<0.90

- FJD
- MD Anderson

Lung Cancer Screening challenges & opportunities

Lack of diagnosis accuracy - a major hurdle to screening adherence & implementation, whilst I-ELCAP study showed 92% survival rate at 15y when diagnosed at stage 1 vs. 5% for stage 4[1]

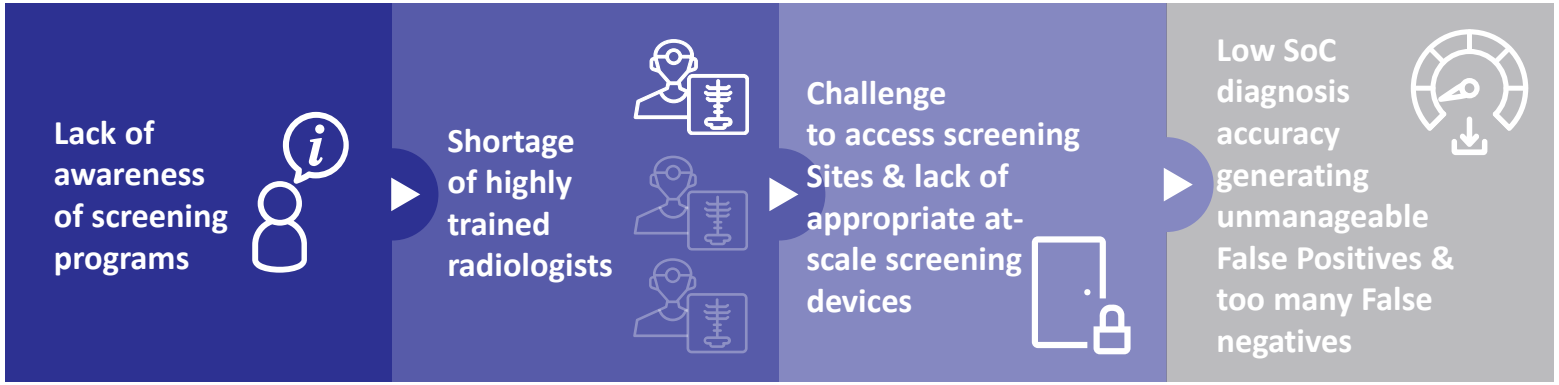
Facts & figures

- **1st cancer killer worldwide**: 1.8M deaths 2022 (19% of all cancer deaths), **2.4M deaths projected in 2030**[2]
- **18% 5-year survival rate**: <25% stage 1 cases (68%-92% survival[3,4]) >40% stage 4 cases (<10% 5-year survival [4] **)**
- **Rising** frequency among **never-smokers** (20% US & UK) [4]
- **4.5% LCS compliance** [5]
- Rising frequency **among never-smokers** [3]
- **New CPT code $650 for AI quantitative CT tissue characterization in the US**

Screening programs

LCS programs implemented		Target population
US	USPSTF guidelines	15M (USPSTF 2021 recommendations) Near future 30M
Europe	UK Poland Croatia Developing in IT/DE/FR	EU T5: 22M (Estimate)
Asia	South Korea & China regionally Japan in study phase	ASIA T3: 100M (Estimate)

Why is LDCT screening % so low in the high-risk populations?



Why eyonis™ LCS?

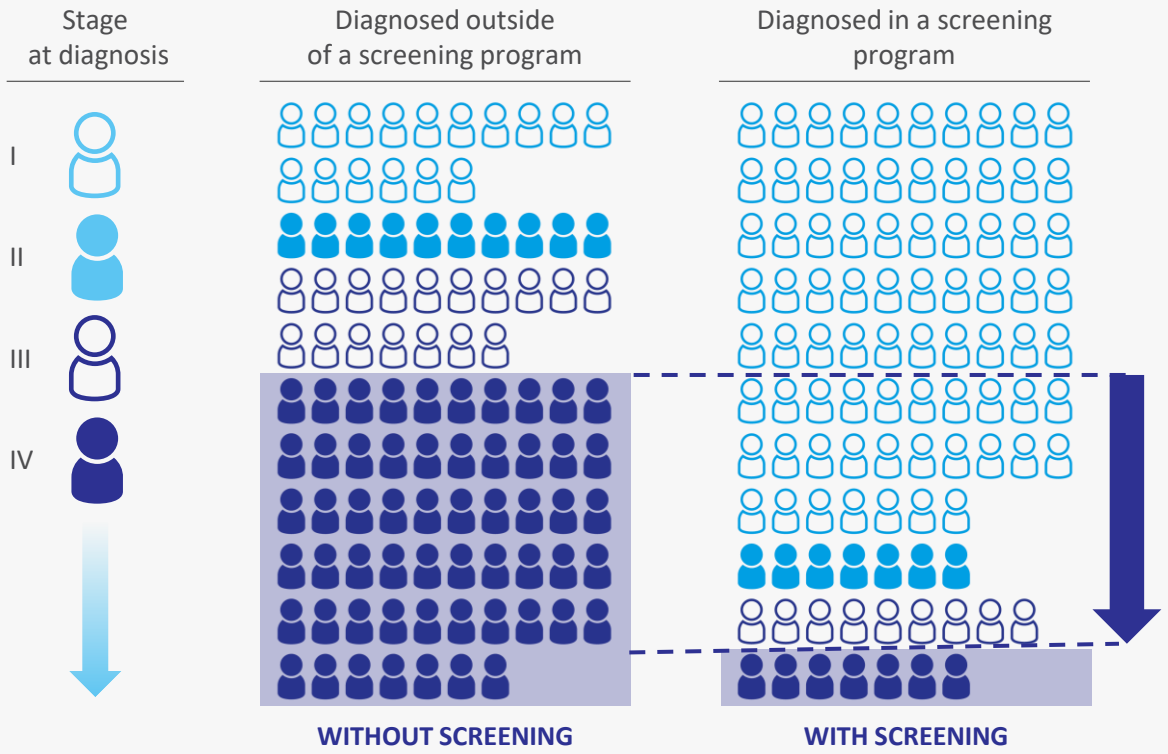
Seamlessly & effortlessly

Sources:
[1] https://www.redjournal.org/article/S0360-3016(19)30110-5/fulltext
[2] Cancer Tomorrow, IARC, Global Cancer Observatory 2020 - WHO
[3] https://www.lungambitionalliance.com/our-initiatives/lung-cancer-screening-the-cost-of-inaction.htm
[4] https://nrdrsupport.acr.org/support/solutions/articles/11000093991-lcsr-state-reports

Landmark clinical studies demonstrated LDCT high value

NLST & NELSON clinical studies results revealed stage shift with annual LDCT & I-ELCAP study showed highest survival when diagnosed at stage 1 - AI LDCT will further increase this trend

Screening programs allow detection of a much higher proportion of lung cancer cases at an early stage compared to routine care



- **NELSON** trial showed LDCT screening impact: **59% cases were early-stage** vs 14% with no screening
- **24% reduction of lung cancer mortality after 10-years vs no screening**
- **NLST showed a 20% deaths decrease with LDCT screening vs chest X-Ray**

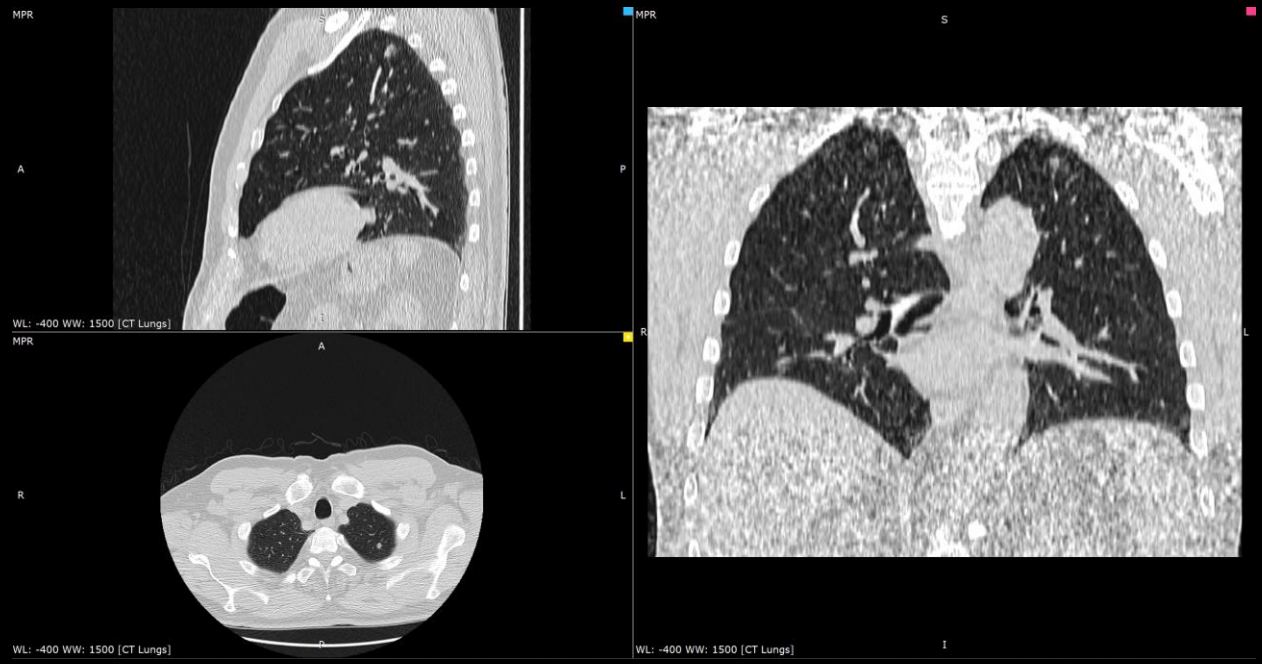
Significant stage shift leading to earlier & better patient care and lower mortality rate

Adapted from Sands et al. (2021). Patient decision-making aid based on combined analysis of existing clinical trials.

NLST: *US based National Lung Screening Trial (53454 participants, 2002-2004)*
NELSON: *Dutch-Belgian Randomized Lung Cancer Screening Trial (15792 participants, 2004-2012)*
LDCT: Low Dose Computed Tomography

Patient example #1

From probably benign to very suspicious



median

eyonis™ LCS

MEDIAN LCS - LUNG NODULES RESULT REPORT

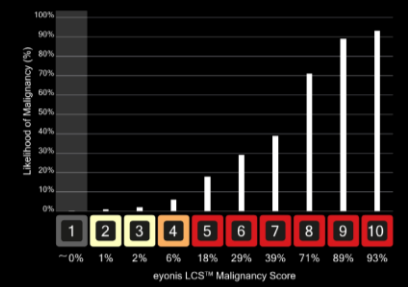
This report contains results automatically generated by Median LCS further to processing Patient "214640" DICOM CT series (see series number below). This report displays only solid and part-solid nodules characterized with a score from 2 and above, and with an average diameter between 4 and 30 mm (see IFU for more details).

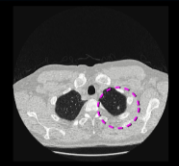
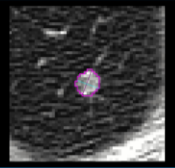
Median LCS output is not intended to replace the clinical judgment of the interpreting physician, and should only be used along with clinical interpretation.

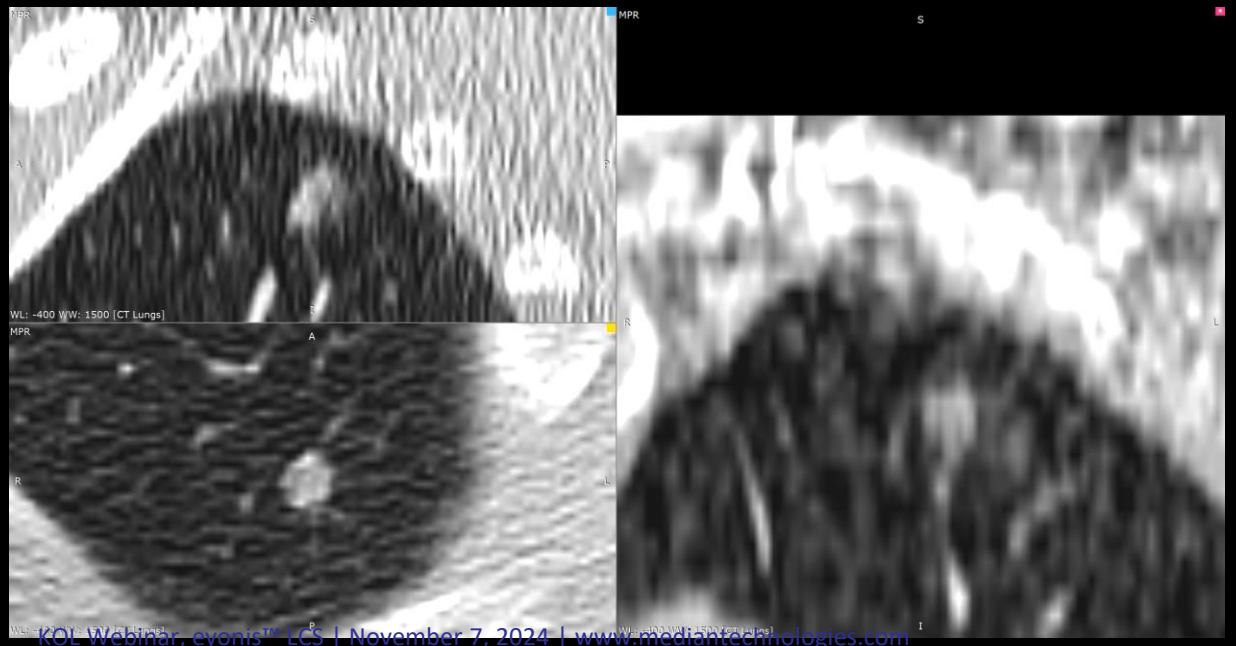
All dates of the present report are in the following format: MM/DD/YYYY HH24:mm:ss

PATIENT:
Name: Anonymised
ID: 214640
DoB (Age): 06/28/2024 (0) / Gender:

SERIES:
Series number: 3
Scan date: 06/28/2024 09:17:51
Scan site:

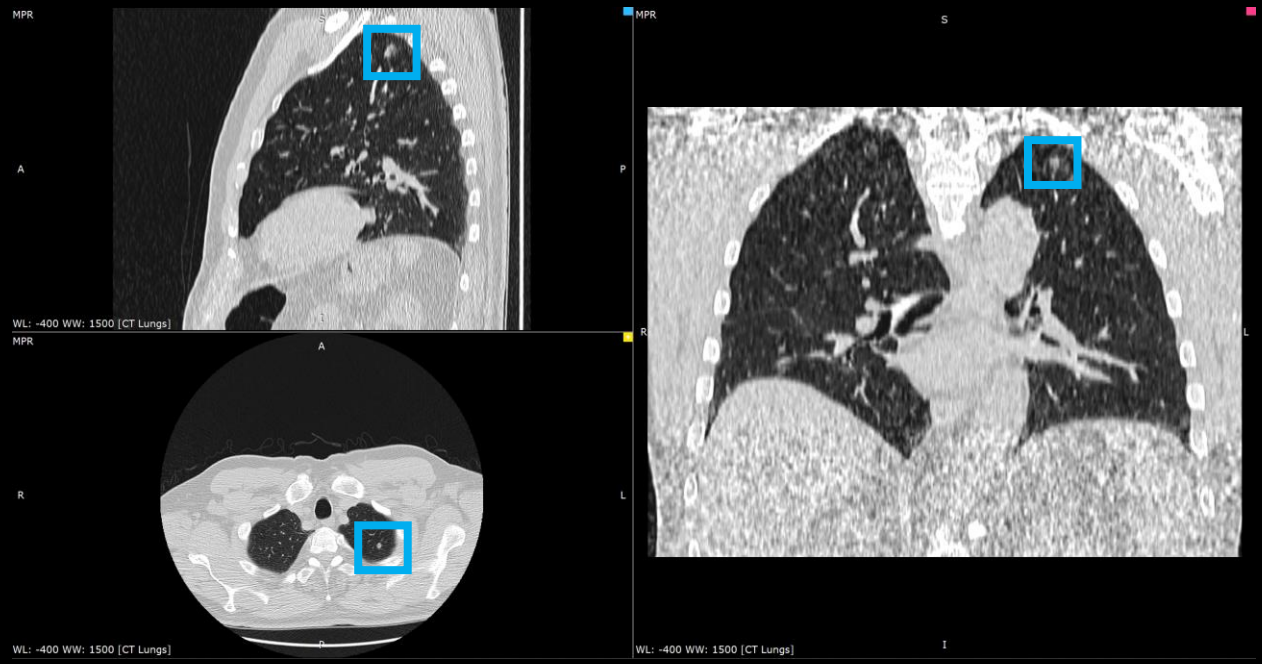


SLICE NUMBER ↑ feet to head ↓ head to feet	MALIGNANCY SCORE	FULL SNAPSHOT	CLOSE-UP SNAPSHOT	DIAMETERS (mm) Long / Short / Avg. VOLUME (mm3)
↑ 121 / 139 ↓ 19 / 139	1 2 3 4 5 6 7 8 9 10 ▲			7.3 / 6 / 6.7 168



Difficult-to-diagnose nodule case 1:
Solid nodule ≥ 6 to < 8 mm in apex area

	Lung Rads 2019	Lung Rads 2022	eyonis™ LCS
Score	3	3	5
Estimated risk of malignancy	1-2% Probably Benign	Not reported Probably Benign	18% Very Suspicious
Recommended Follow-up	6-month LDCT	6-month LDCT	Swift additional diagnostics: Chest CT W/ or W/out contrast and/or PET/CT and/or tissue sampling



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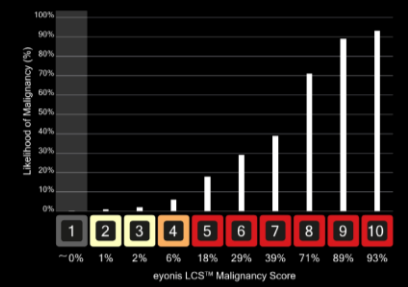

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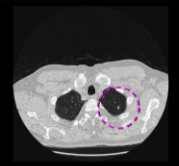
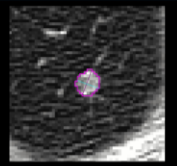
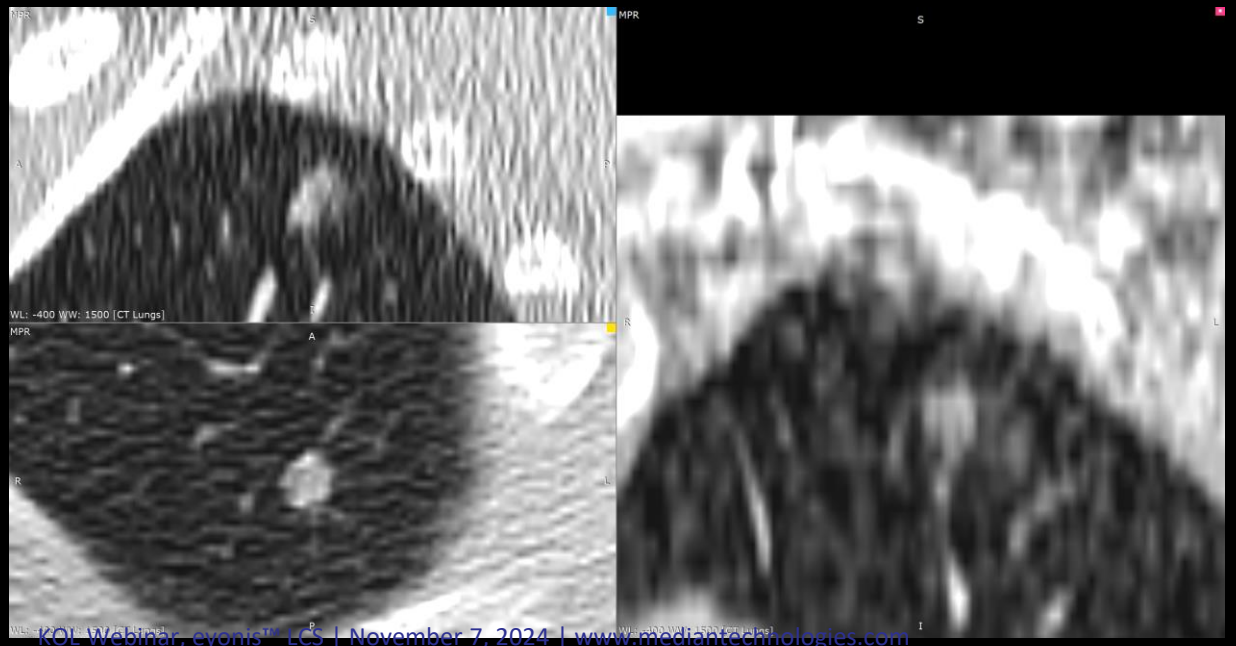
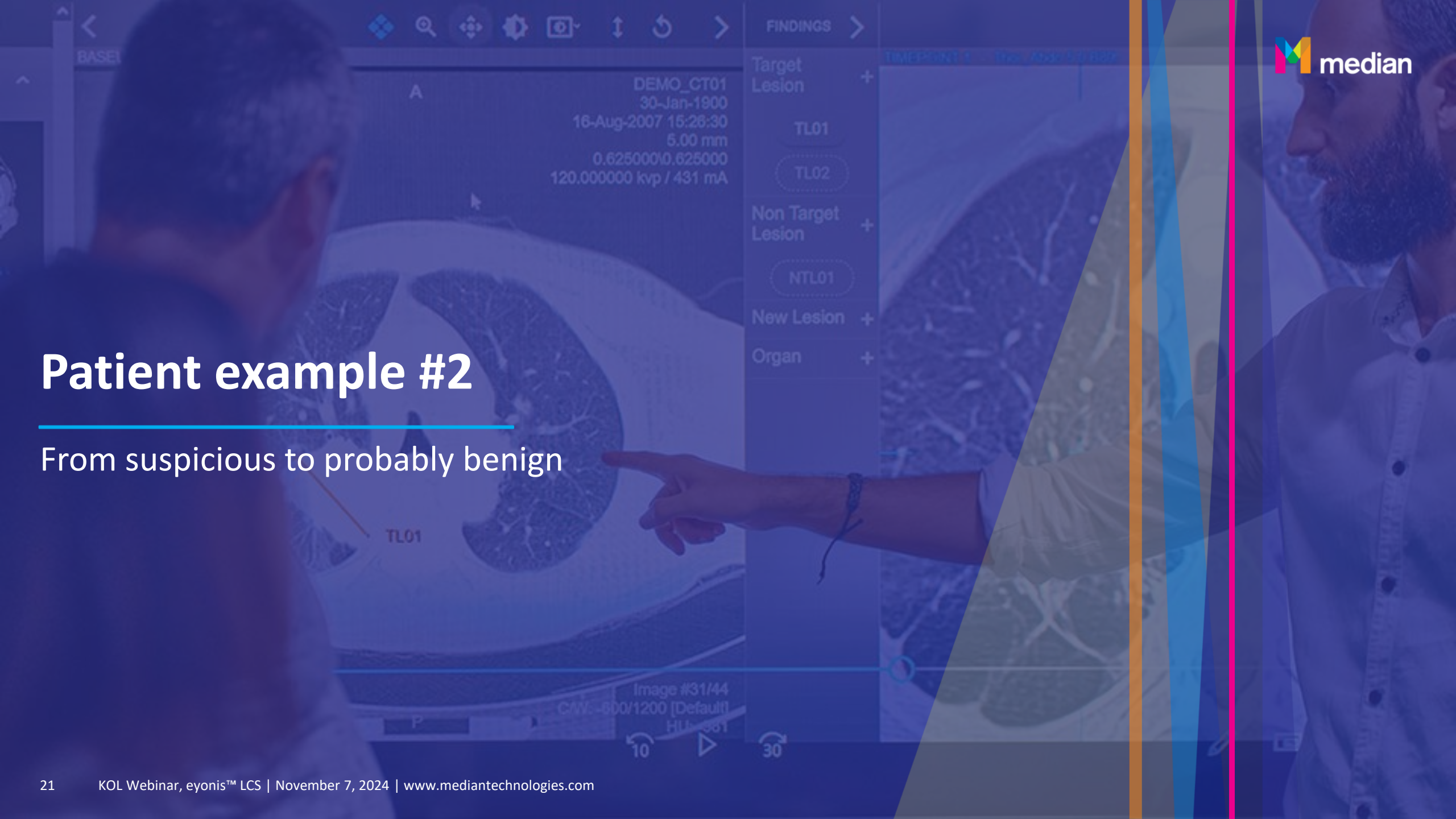
↑ 121 / 139 ↓ 19 / 139	1 2 3 4 5 6 7 8 9 10 ▲			7.3 / 6 / 6.7 168



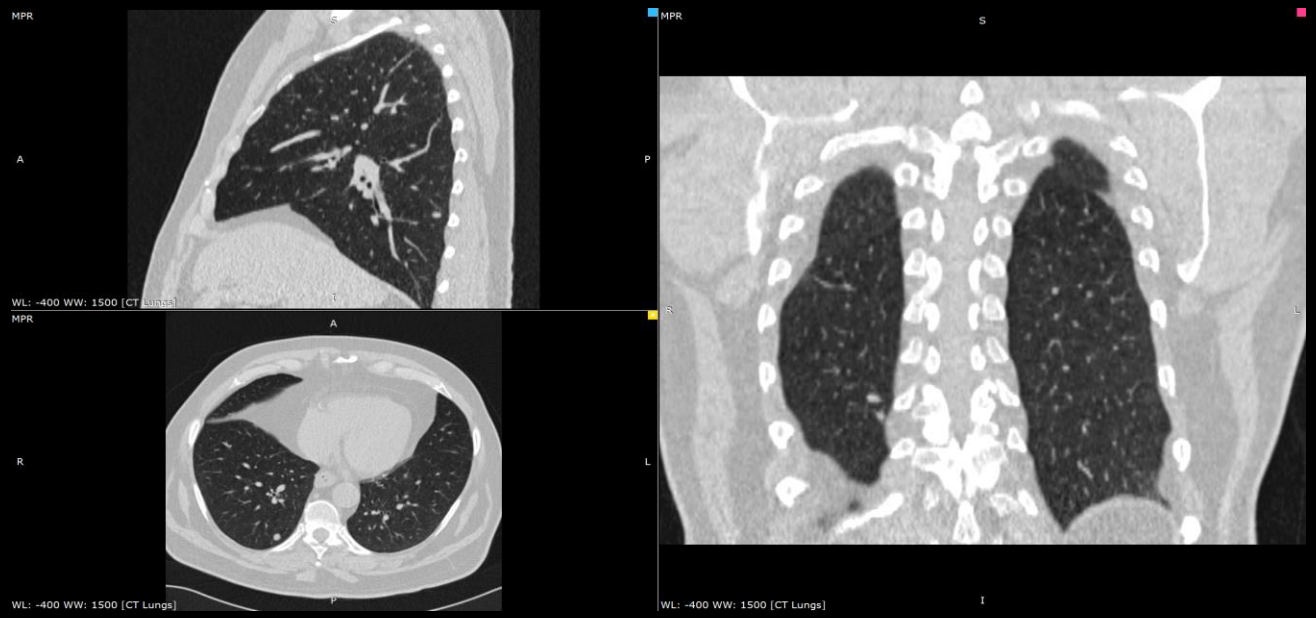
Difficult-to-diagnose nodule case 1:
Solid nodule ≥ 6 to < 8 mm in apex area

	Lung Rads 2019	Lung Rads 2022	eyonis™ LCS
Score	**3**	**3**	**5**
Estimated risk of malignancy	**1-2% Probably Benign**	**Not reported Probably Benign**	**18% Very Suspicious**
Recommended Follow-up	**6-month LDCT**	**6-month LDCT**	**Swift additional diagnostics: Chest CT W/ or W/out contrast and/or PET/CT and/or tissue sampling**



Patient example #2

From suspicious to probably benign



median

eyonis™ LCS

MEDIAN LCS - LUNG NODULES RESULT REPORT

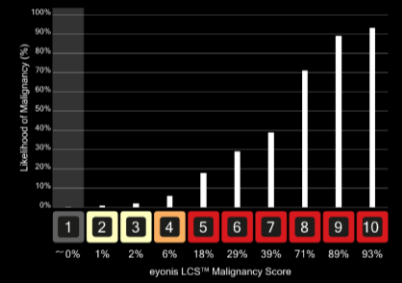
This report contains results automatically generated by Median LCS further to processing Patient "109682" DICOM CT series (see series number below). This report displays only solid and part-solid nodules characterized with a score from 2 and above, and with an average diameter between 4 and 30 mm (see IFU for more details).

Median LCS output is not intended to replace the clinical judgment of the interpreting physician, and should only be used along with clinical interpretation.

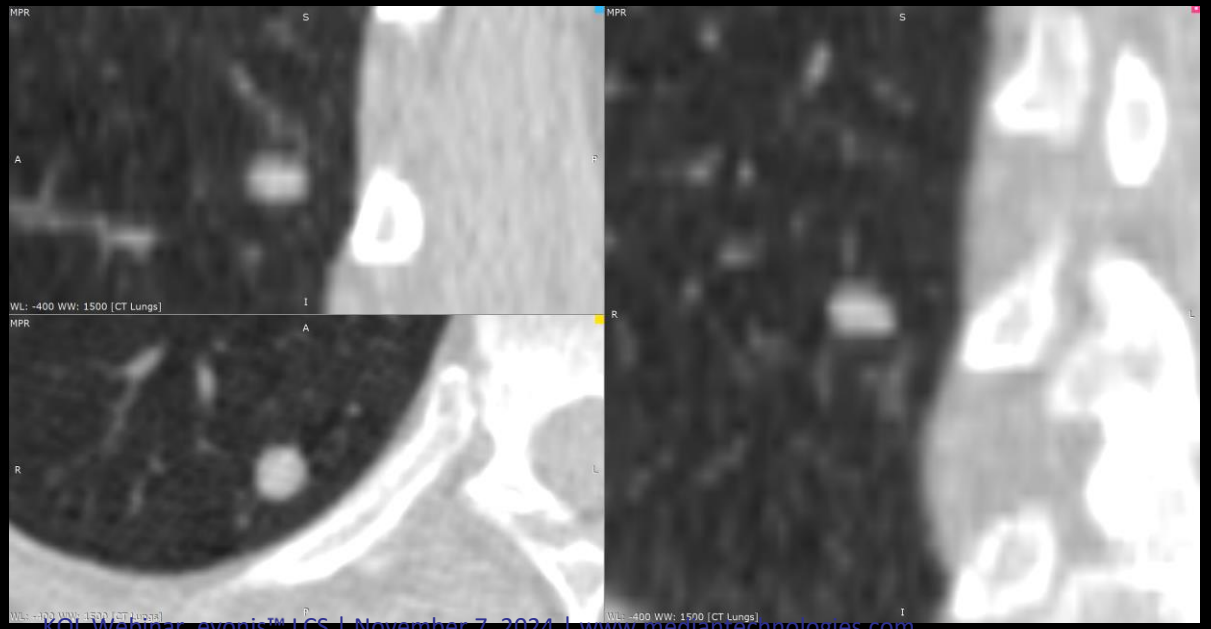
All dates of the present report are in the following format: MM/DD/YYYY HH24:mm:ss

PATIENT:
Name: Anonymised
ID: 109682
DoB (Age): 06/28/2024 (0) / Gender:

SERIES:
Series number: 2
Scan date: 06/28/2024 09:42:04
Scan site:



SLICE NUMBER ↑ feet to head ↓ head to feet	MALIGNANCY SCORE	FULL SNAPSHOT	CLOSE-UP SNAPSHOT	DIAMETERS (mm) Long / Short / Avg. VOLUME (mm3)
↑47 / 146 ↓100 / 146				10.3 / 8.7 / 9.5 289



Difficult-to-diagnose nodule case 2:
Nodule ≥ 8 to < 15 mm w/ solid component 289 mm³

	Lung Rads 2019	Lung Rads 2022	eyonis™ LCS
Score	**4A**	**4A**	**2**
Estimated risk of malignancy	**5-15% Suspicious**	**Not reported Suspicious**	**1% Lowly Suspicious**
Recommended Follow-up	**3-month LDCT and PET/CT since > 268 mm³**	**3-month LDCT and PET/CT since > 268 mm³**	**6-month LDCT**

median

eyonis™ LCS

MEDIAN LCS - LUNG NODULES RESULT REPORT

This report contains results automatically generated by Median LCS further to processing Patient "109682" DICOM CT series (see series number below). This report displays only solid and part-solid nodules characterized with a score from 2 and above, and with an average diameter between 4 and 30 mm (see IFU for more details).

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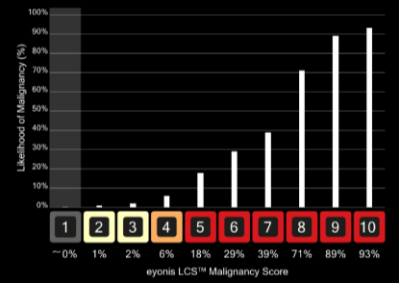
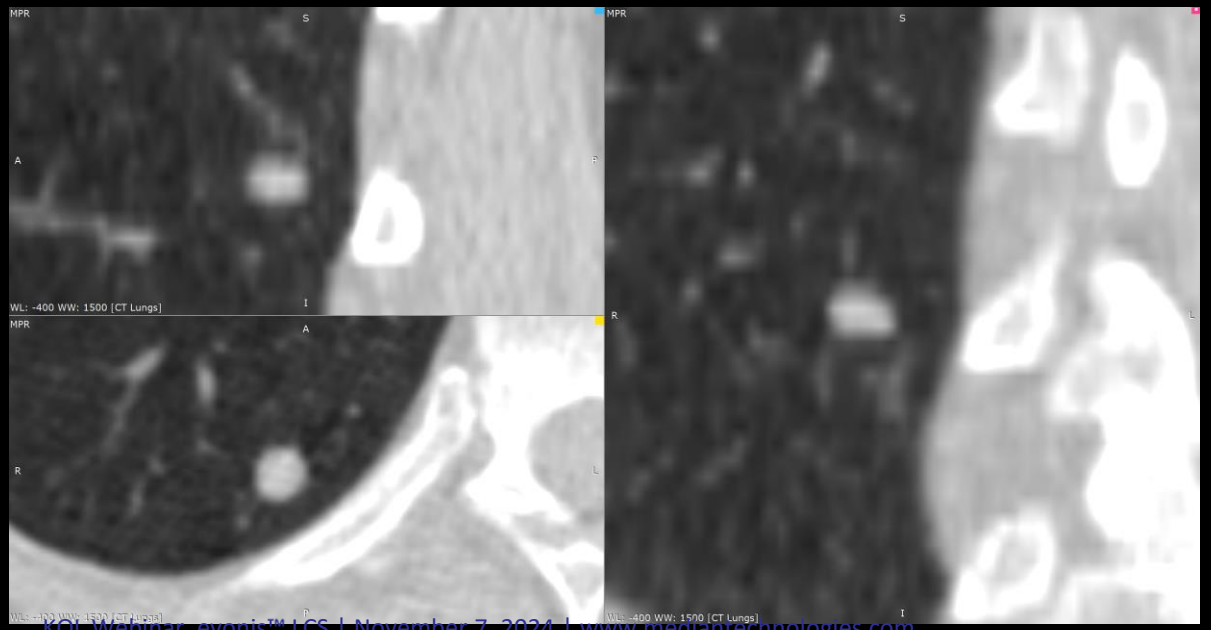
Scan site:



SLICE NUMBER ↑ feet to head ↓ head to feet	MALIGNANCY SCORE	FULL SNAPSHOT	CLOSE-UP SNAPSHOT	DIAMETERS (mm) Long / Short / Avg. VOLUME (mm3)
↑47 / 146 ↓100 / 146				10.3 / 8.7 / 9.5 289



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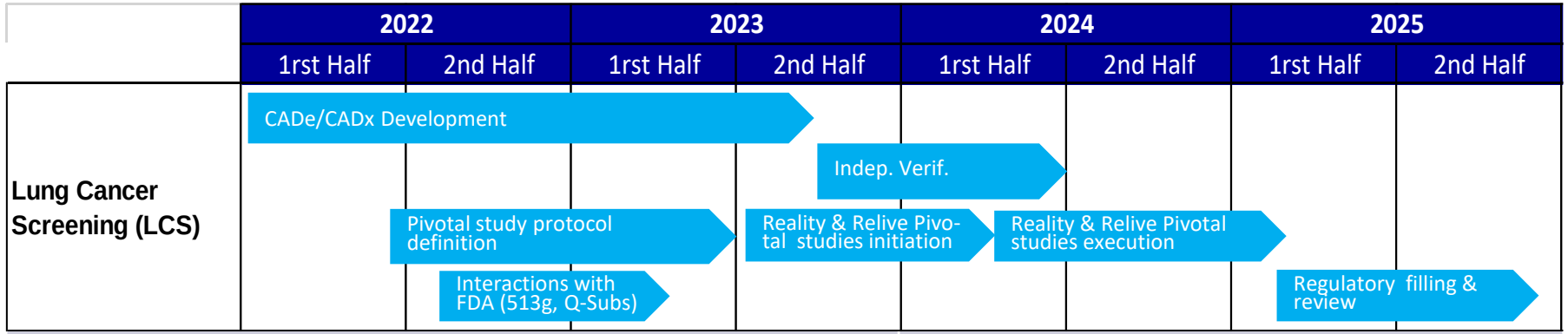
Nodule ≥ 8 to < 15 mm w/ solid component 289 mm³

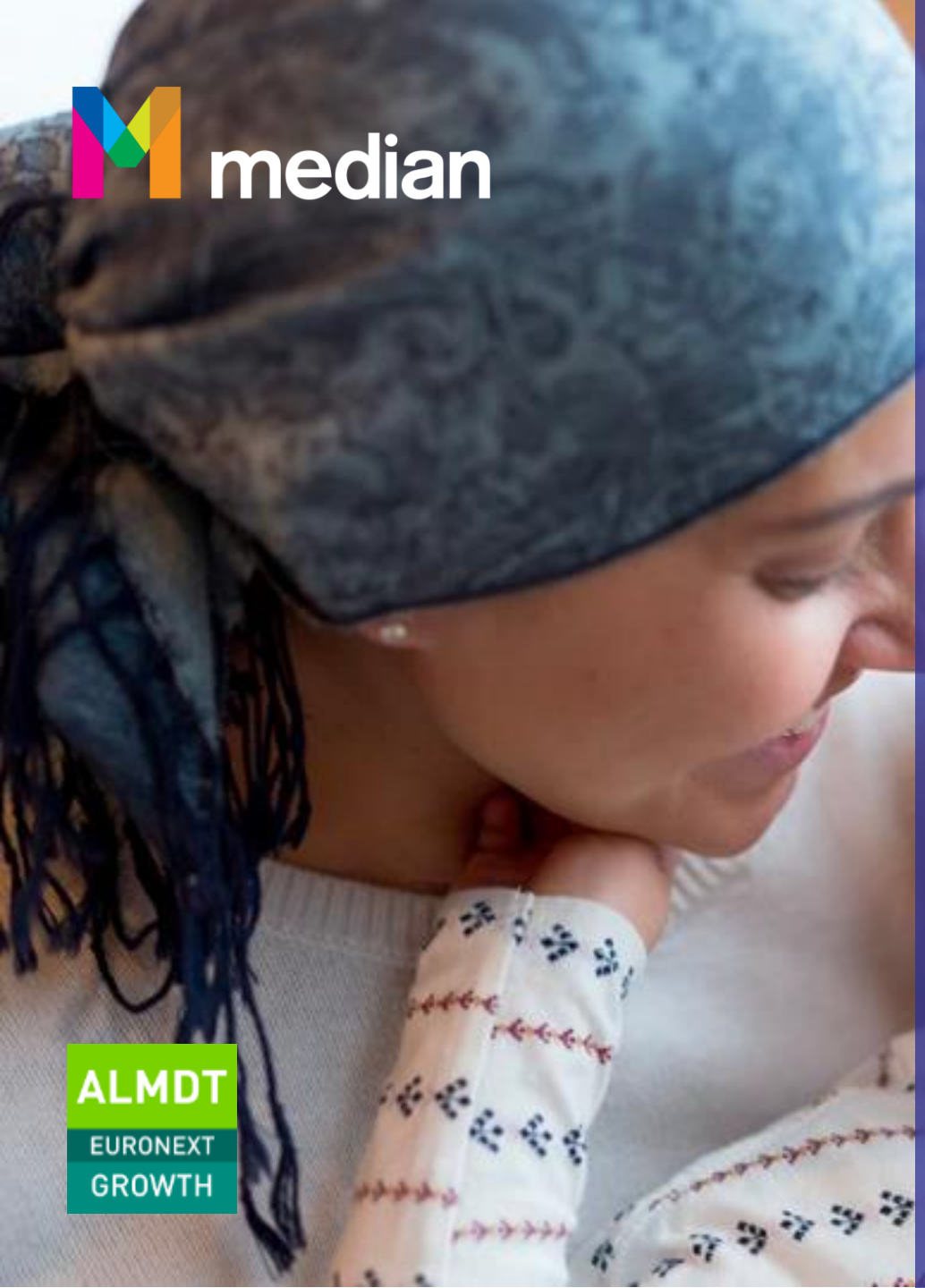
	Lung Rads 2019	Lung Rads 2022	eyonis™ LCS
Score	**4A**	**4A**	**2**
Estimated risk of malignancy	**5-15% Suspicious**	**Not reported Suspicious**	**1% Lowly Suspicious**
Recommended Follow-up	**3-month LDCT and PET/CT since > 268 mm³**	**3-month LDCT and PET/CT since > 268 mm³**	**6-month LDCT**

eyonis™ LCS next steps

Relive MRMC clinical study, regulatory fillings & US pre-commercial GotoMarket activities



eyonis™ LCS Standalone Study (MT-LCS-002, REALITY)	Finalized - All primary and secondary endpoints successfully passed
eyonis™ LCS Multi-Reader Multi-Case Study (MRMC, MT-LCS-004, RELIVE)	Progressing as planned. Topline data expected in Q1 2025
CADe/CADx SaMD eyonis™ LCS filing (FDA 510(k))	In preparation Scheduled for submission in H1 2025
CADe/CADx SaMD eyonis™ LCS filing (CE mark)	In preparation Scheduled for submission in H1 2025
Pre-Commercial activities	First centers installations Q2/3 2025
Market Access & Reimbursement roll-out	GtM deployment Q2/3 2025



median

ALMDT
EURONEXT
GROWTH

Our Core Values

Leading innovation with purpose
Combine the spirit of innovation with our passion and conviction to help cure cancer and other debilitating diseases.

Committing to quality in all we do
Be dedicated to quality in everything we do. Quality begins with us and we are committed to it.

Supporting our customers in achieving their goals
Listen to the needs of our customers and help make their goals our goals through our innovation, imaging expertise, superior services, and quality solutions.

Putting the patient first
There is a person at the other end of the images we analyze who is counting on us to do everything we can to help make them healthier.

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