



# New Horizons in Fighting Lung Cancer: eyonis™ LCS RELIVE study results & next steps towards marketing authorizations

Live Webcast - February 4, 2025

Speaker: Fredrik Brag, CEO and Founder of Median Technologies

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# 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<sup>(1)</sup>

## Facts & figures

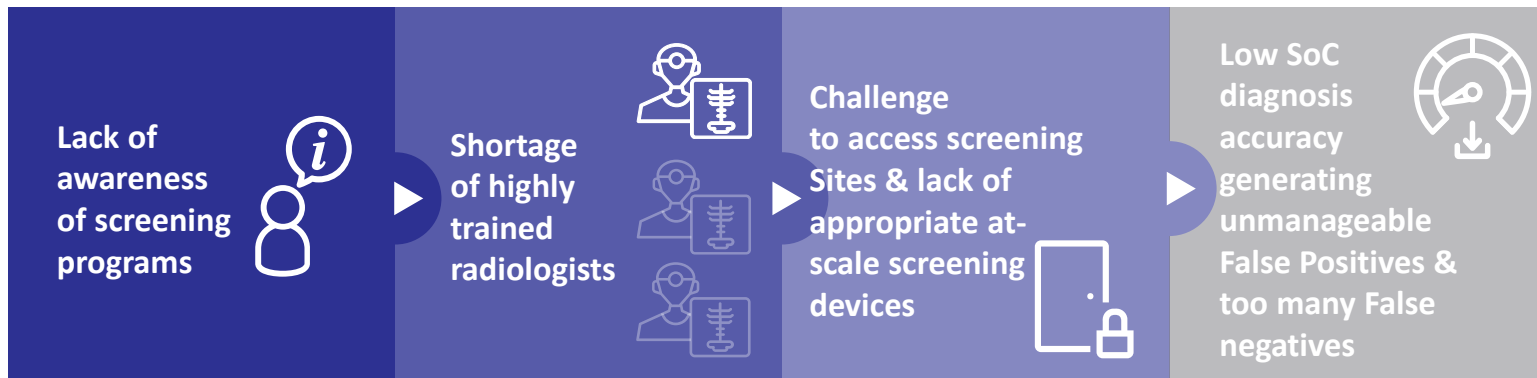


- **1st cancer killer worldwide:** 1.8M deaths 2022 (19% of all cancer deaths), 2.4M deaths projected in 2030<sup>(2)</sup>
- **18% 5-year survival rate:** <25% stage 1 cases (68%-92% survival<sup>(3,4)</sup>) >40% stage 4 cases (<10% 5-year survival<sup>(4)</sup>)
- **Rising frequency among never-smokers**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

## Screening programs

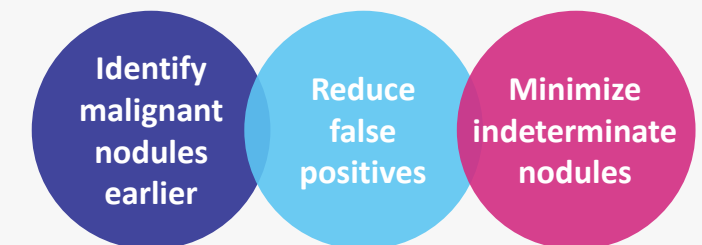
LCS programs implemented		Target population
US	USPSTF guidelines	15M (USPSTF 2021 recommendations) Near future 30M
Europe	UK Poland Croatia Germany Developing in IT/DE/FR	EU T5: 22M (Estimate)
Asia	South Korea & China regionally Japan in study phase	ASIA T3: 100M (Estimate)

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



## Why eyonis™ LCS?




















Seamlessly & effortlessly



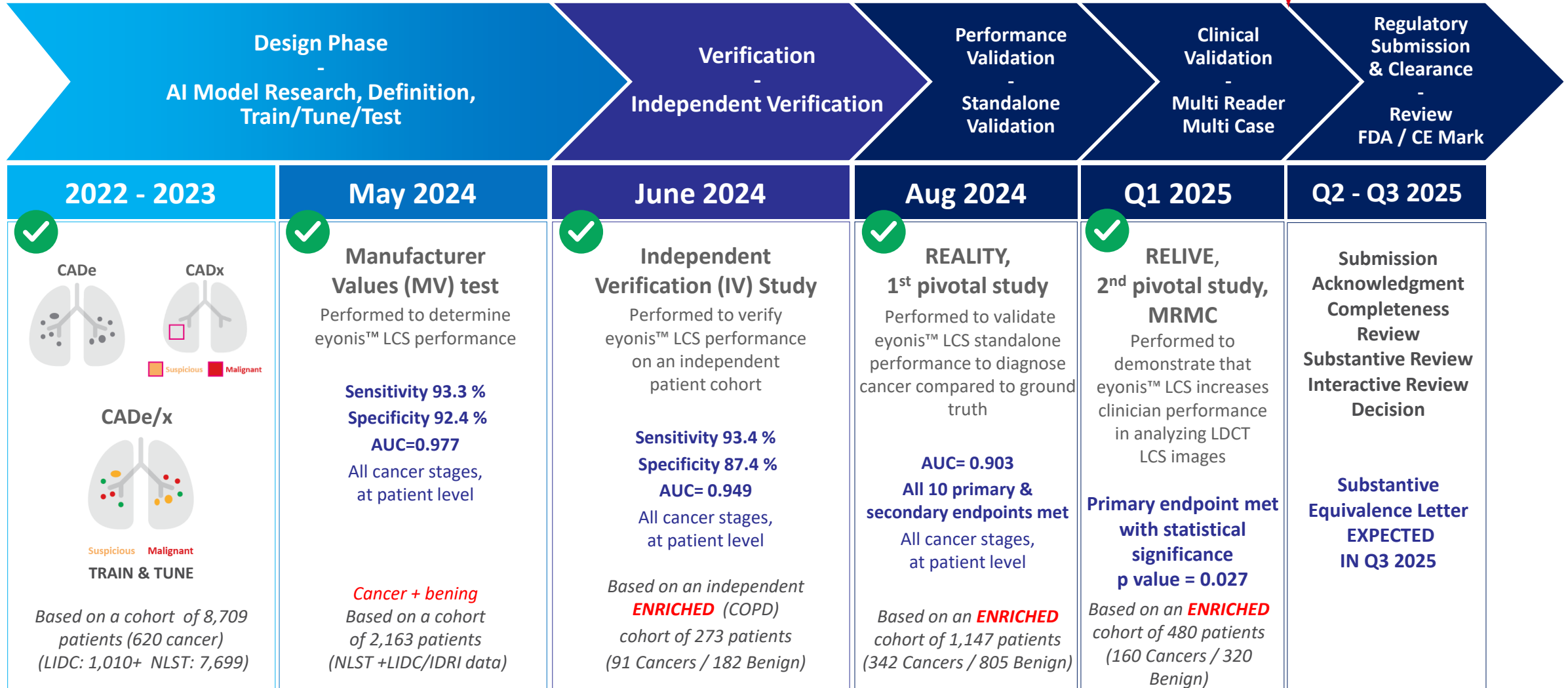
Sources:  
 [1] [https://www.redjournal.org/article/S0360-3016\(19\)30110-5/fulltext](https://www.redjournal.org/article/S0360-3016(19)30110-5/fulltext)  
 [2] Cancer Tomorrow, IARC, Global Cancer Observatory 2020 - WHO  
 [3] <https://www.lungambitionalliance.com/our-initiatives/lung-cancer-screening-the-cost-of-inaction.htm>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

# Median eyonis™ LCS is the Only SaMD-Candidate with CADe/CADx Features Designed for Lung Cancer Screening Indication



<p><b>DIRECT</b></p>  <p><b>CADe CADx</b></p>	<p><b>INDIRECT</b></p>  <p>Not in US</p>  <p>Not LCS indication</p> <p><b>CADx</b></p>
<p><b>COMPARABLE</b></p>       <p><b>Liquid Biopsy</b></p>	<p><b>INDIRECT</b></p>           <p><b>CADe</b></p>

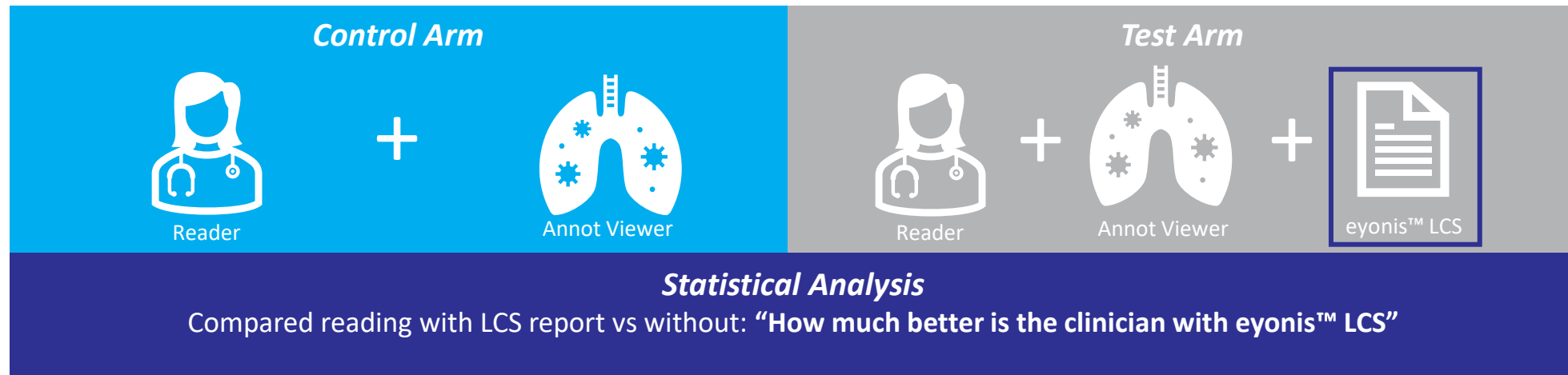
# eyonis™ LCS Has Achieved Continuous Success, Supporting Regulatory Submissions in Q2 2025



# eyonis™ LCS Pivotal RELIVE Trial (MRMC Trial)

MRMC study design plays a key role in the translation of novel imaging tools, such as AI algorithms, to clinical practice.

- 480 patients (160 cancers, 320 benign cases) and 16 readers
- Enriched cohort with a 1:2 distribution of cancer positive and cancer negative patients
- Paired-split-plot design
- **Objective: Demonstrate that eyonis™ LCS improves clinician performance in analyzing LDCT lung screening scans, reducing FPs and unneeded follow-up procedures**

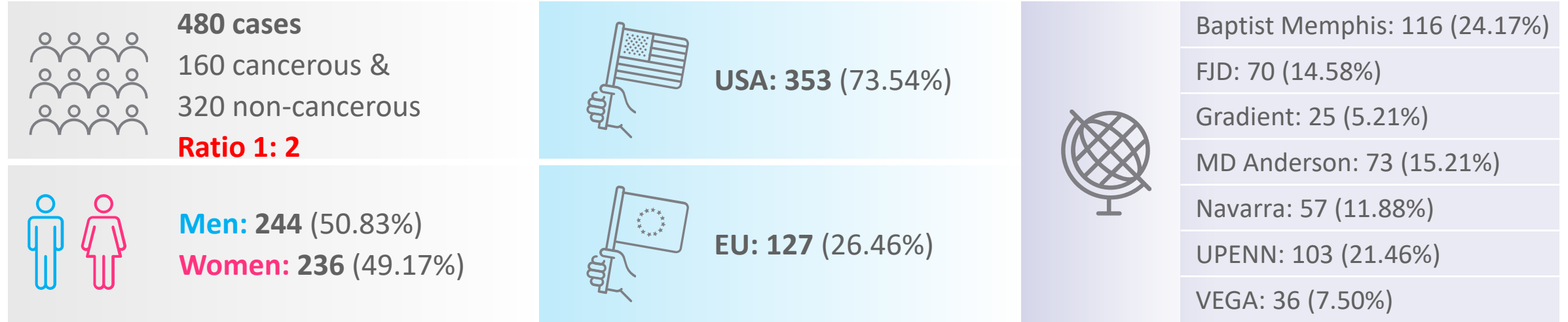


## Primary Endpoint

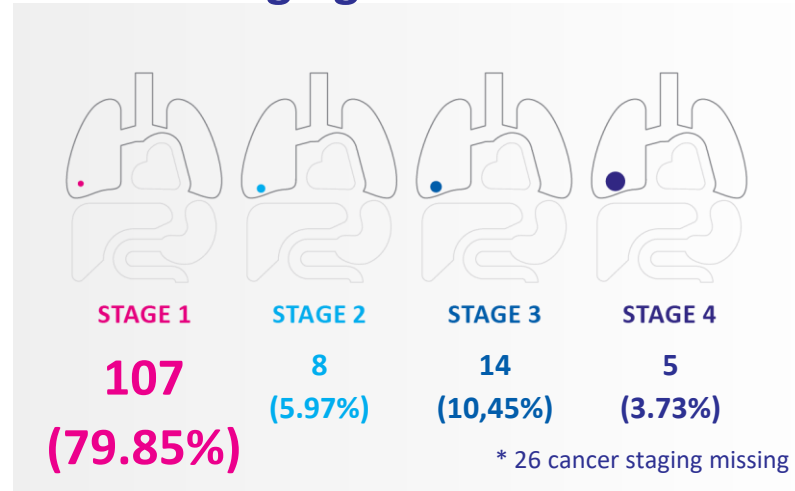
Difference between with & without Median LCS in **AUROC** values that measures the modality performances on patient level data. **Superiority with LCS report vs without to be achieved.**

# RELIVE Study at Glance

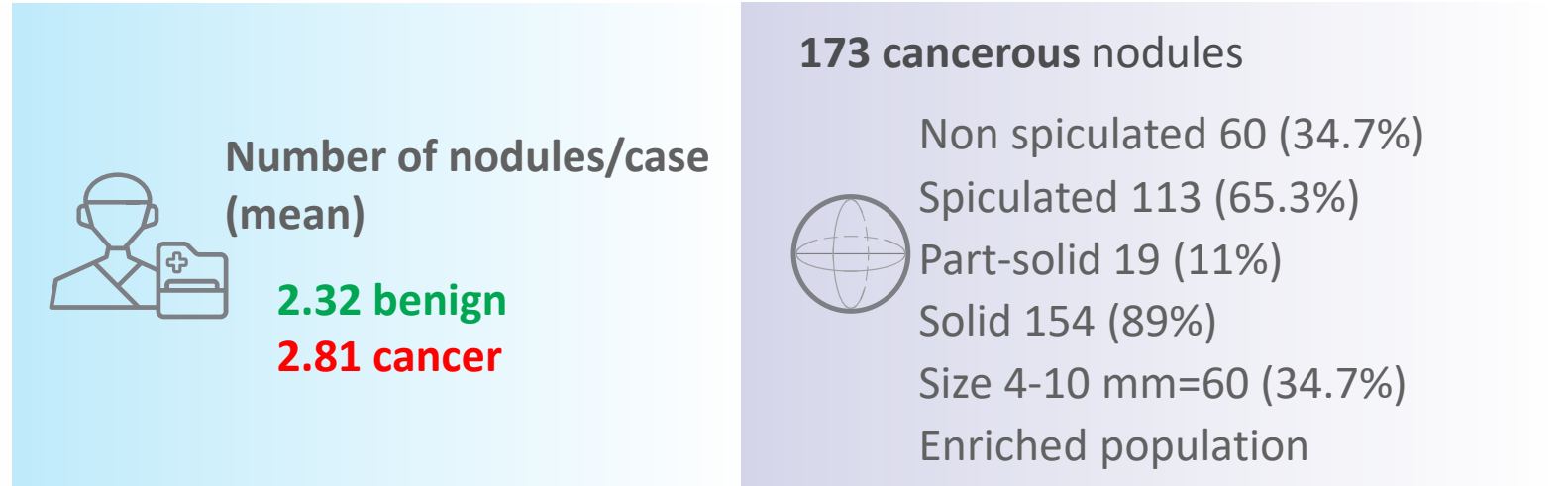
## Cohort & Data Sources



## Cancer staging\*



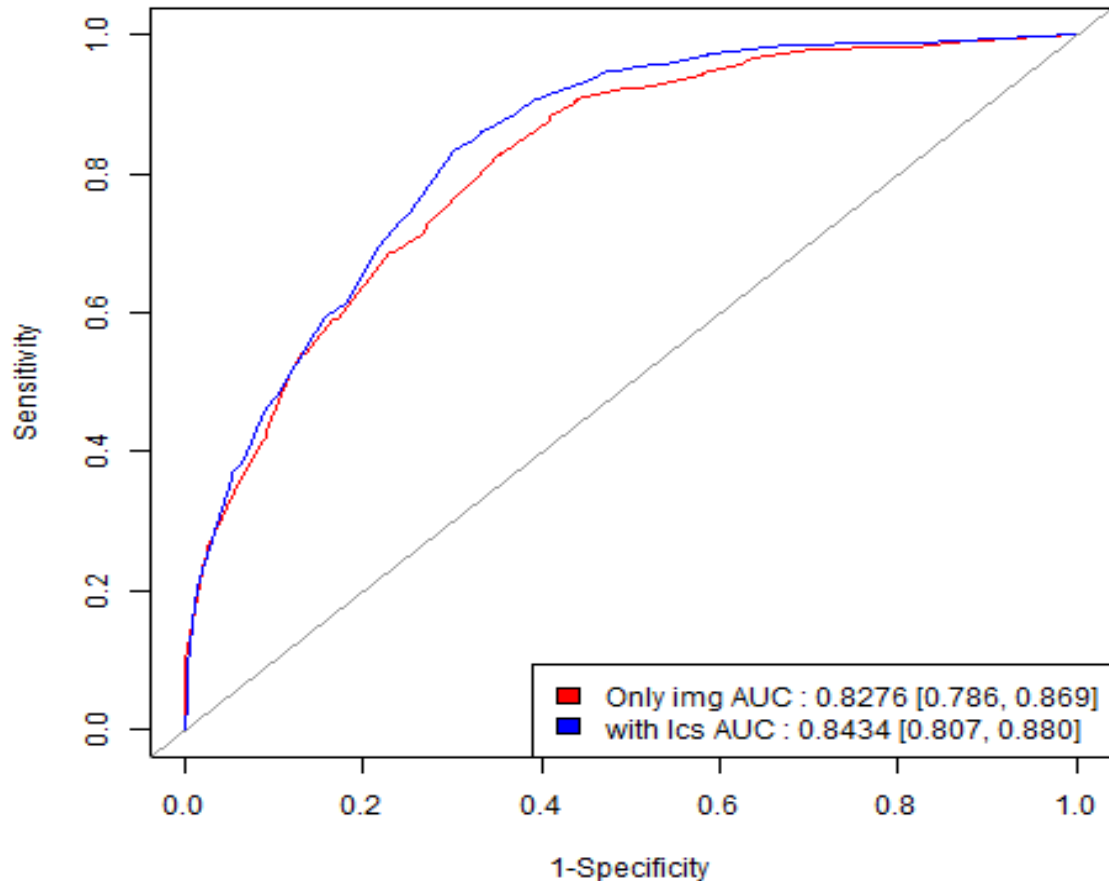
## Nodules characteristics



# RELIVE Study Results

Primary endpoint successfully passed (enriched population)

Graph 3.1 ROC analysis by arm



- Median is the first & only SaMD manufacturer who opted for Paired Split Plot design\* further to FDA pre-sub discussions.
- Average years of experience of readers very high: more than 15-years specialized chest radiologists
- RELIVE primary endpoint is a superiority test:  $\Delta$  AUC (with LCS – reader alone) > 0.

**$\Delta$  AUC = 0.016, p value = 0.027**

- **Since it was successfully met, Median can file for Marketing Authorization.**



## Secondary endpoints analysis

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### RELIVE SECONDARY ENDPOINTS

$\text{Sensitivity}_{\text{with LCS}} - \text{Sensitivity}_{\text{Reader alone}} > -0.1$  (Non inferiority)

$\text{Specificity}_{\text{with LCS}} - \text{Specificity}_{\text{Reader alone}} > -0.1$  (Non inferiority)

$\text{AUC-LROC}_{\text{with LCS}} > \text{AUC-LROC}_{\text{Reader alone}}$  ( $\Delta \text{LROC} > 0$ )

$\text{Recall Specificity}_{\text{with LCS}} - \text{Recall Specificity}_{\text{Reader alone}} > -0.1$  (Non inferiority)

$\text{Recall Sensitivity}_{\text{with LCS}} - \text{Recall Sensitivity}_{\text{Reader alone}} > -0.1$  (Non inferiority)

$\text{Sensitivity}_{\text{with LCS}} > \text{Sensitivity}_{\text{reader alone}}$  (Superiority)

$\text{Specificity}_{\text{with LCS}} > \text{Specificity}_{\text{Reader alone}}$  (Superiority)

$\text{Recall Specificity}_{\text{with LCS}} > \text{Recall Specificity}_{\text{Reader alone}}$  (Superiority)

$\text{Recall Sensitivity}_{\text{with LCS}} > \text{Recall Sensitivity}_{\text{Reader alone}}$  (Superiority)

$\text{Analysis Time}_{\text{with LCS}} < \text{Analysis Time}_{\text{Reader alone}}$

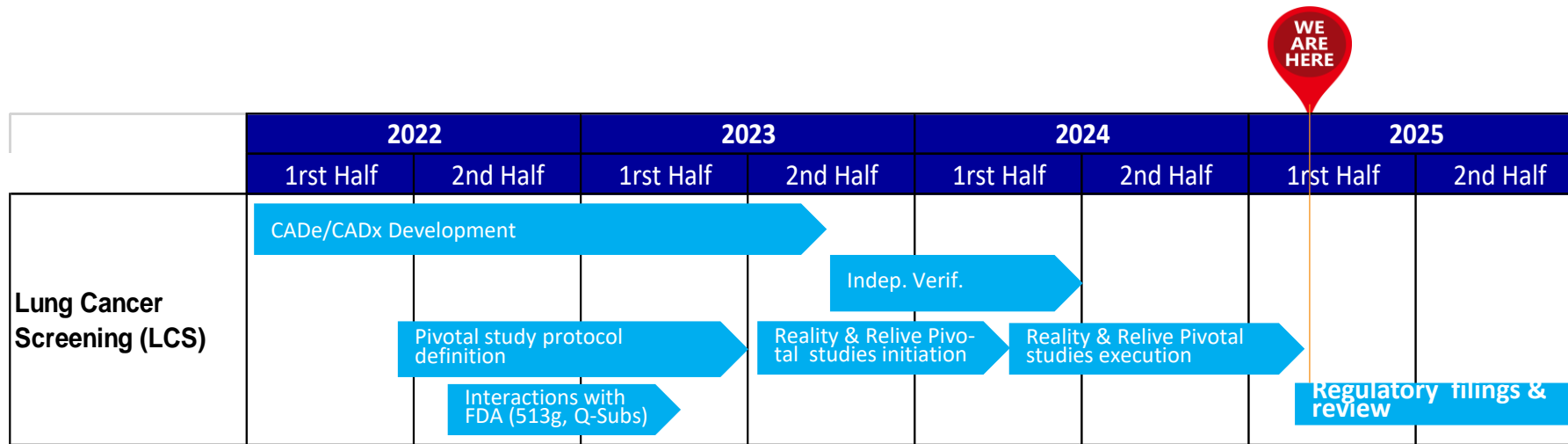
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*“When  $\Delta \text{AUC}$  is the primary endpoint, while sensitivity and specificity are secondary endpoints, a two-family gatekeeping approach should be used to control the study-wise type I error rate, where sensitivity and specificity are only tested if the primary endpoint is met.”*

(Obuchowski NA. Published Online: February 15, 2022  
<https://doi.org/10.1148/radiol.211593>)

# 2025 Key Milestones for eyonis™ LCS

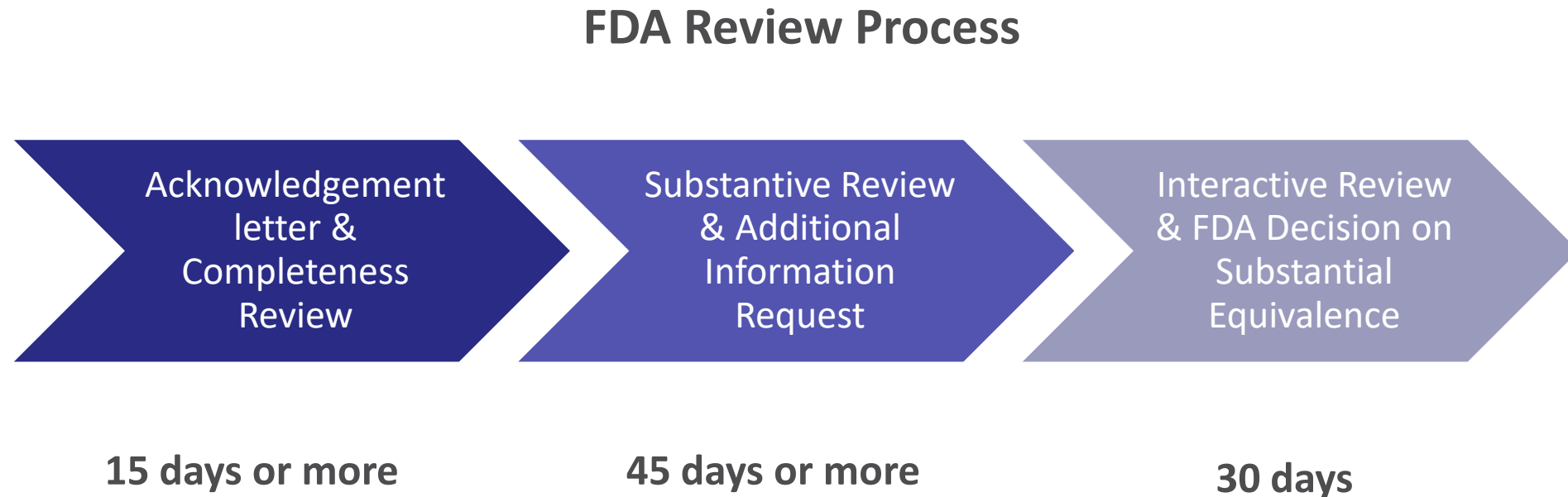
Now entering the last segment of clinic-regulatory pathway: Regulatory filings & Review



eyonis™ LCS filings (FDA 510(k) and CE marking)	Q2 2025
Expected FDA clearance assuming normal review time	Q3 2025
Expected CE marking assuming normal review time	Q1 2026

# 2025 Key Milestones for eyonis™ LCS

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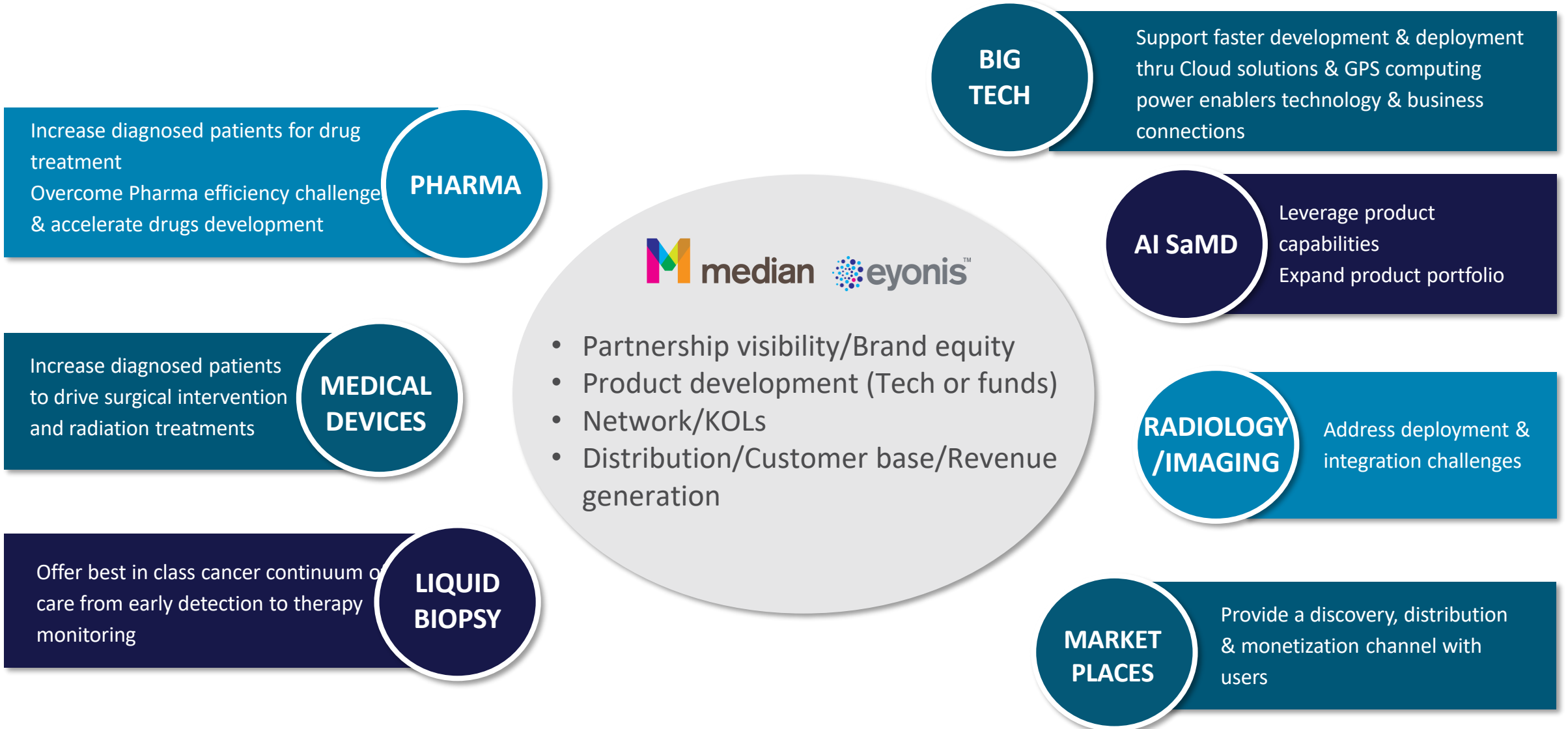
# Median Is Already Executing on its eyonis™ LCS Launch Strategy Roadmap

- 1** Pursue engagement with US KOLs pulmonologists & radiologists, and initiate device trial use under research agreements
- 2** Engage payers with Health Economic Outcomes Model for reimbursement discussions and launch health economic studies
- 3** Reach-out to distribution partners
- 4** Prepare for setting up US commercial organization

# Median eyonis™ LCS Partnerships & Opportunities



Seven segments for partnerships and potential opportunities



# Company Financing

# Company cash runway extended from Q2 to at least Q4 2025

Operational improvements to enhance profitability of the iCRO Business Unit	Ongoing, higher prices, lower costs
Extension of the 2020 EIB loan maturity until October 2025	Agreement signed, shareholder approval pending
New EIB facility of €37.5 million, final due diligence process ongoing	Finalization of legal documentation expected in Q1 2025 Project description available on <a href="#">EIB website</a>
€10 million financing agreement signed on January 23, 2024, with IRIS	First €4 million tranche drawn on January 23, 2025

# Next Steps and Q & A Session



- Major interest from U.S. financial markets
- Median to present at the TD Cowen Healthcare Conference in Boston early March
- Strategic partnerships expected to materialize in the coming months, prior to market launch



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## 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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