



Enabling Lung Cancer Screening with iBiopsy[®] AI-based Software as Medical Device

ECR 2022 – AI Theater

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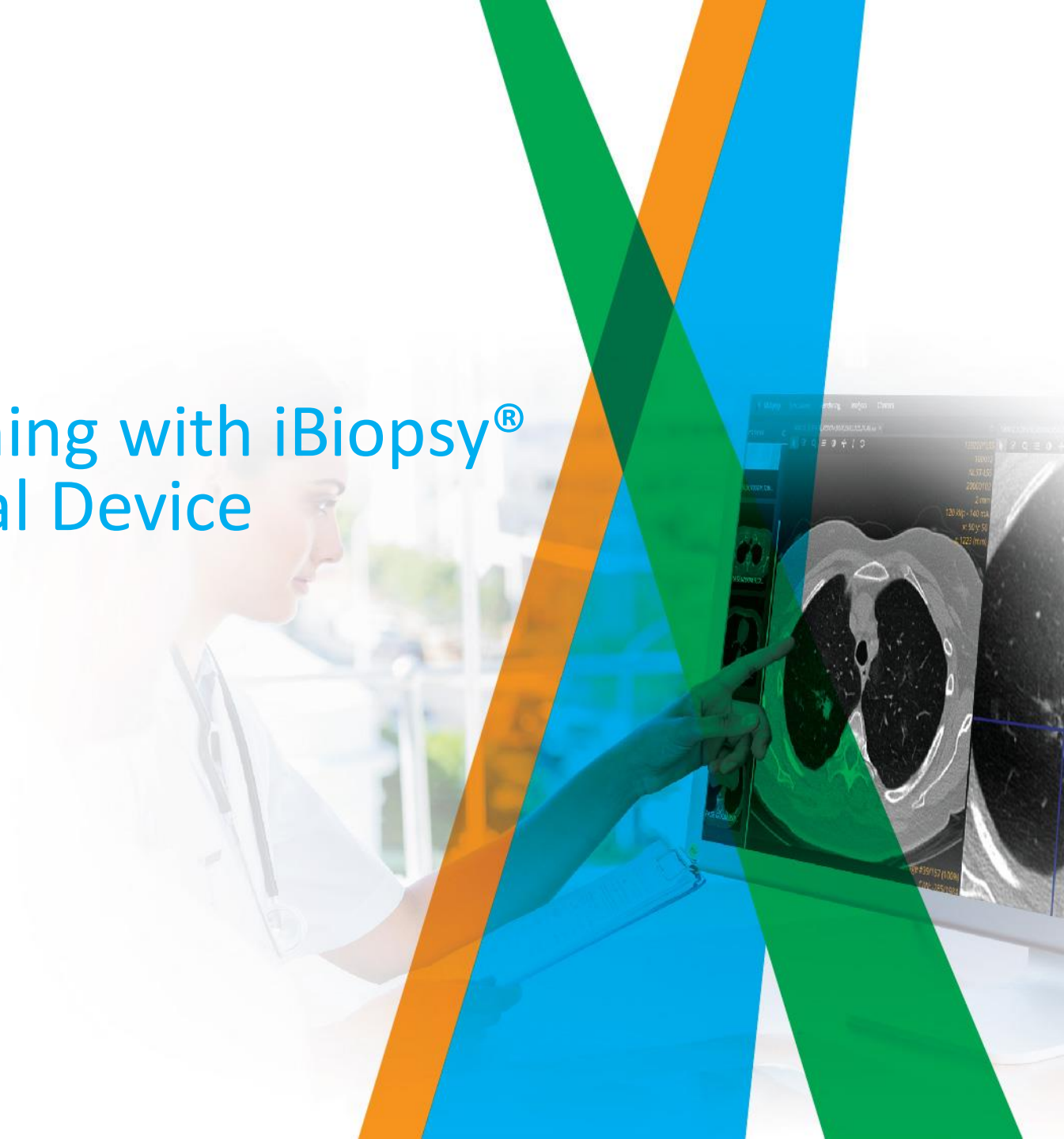
And the entire iBiopsy[®] team!

13/07/2022



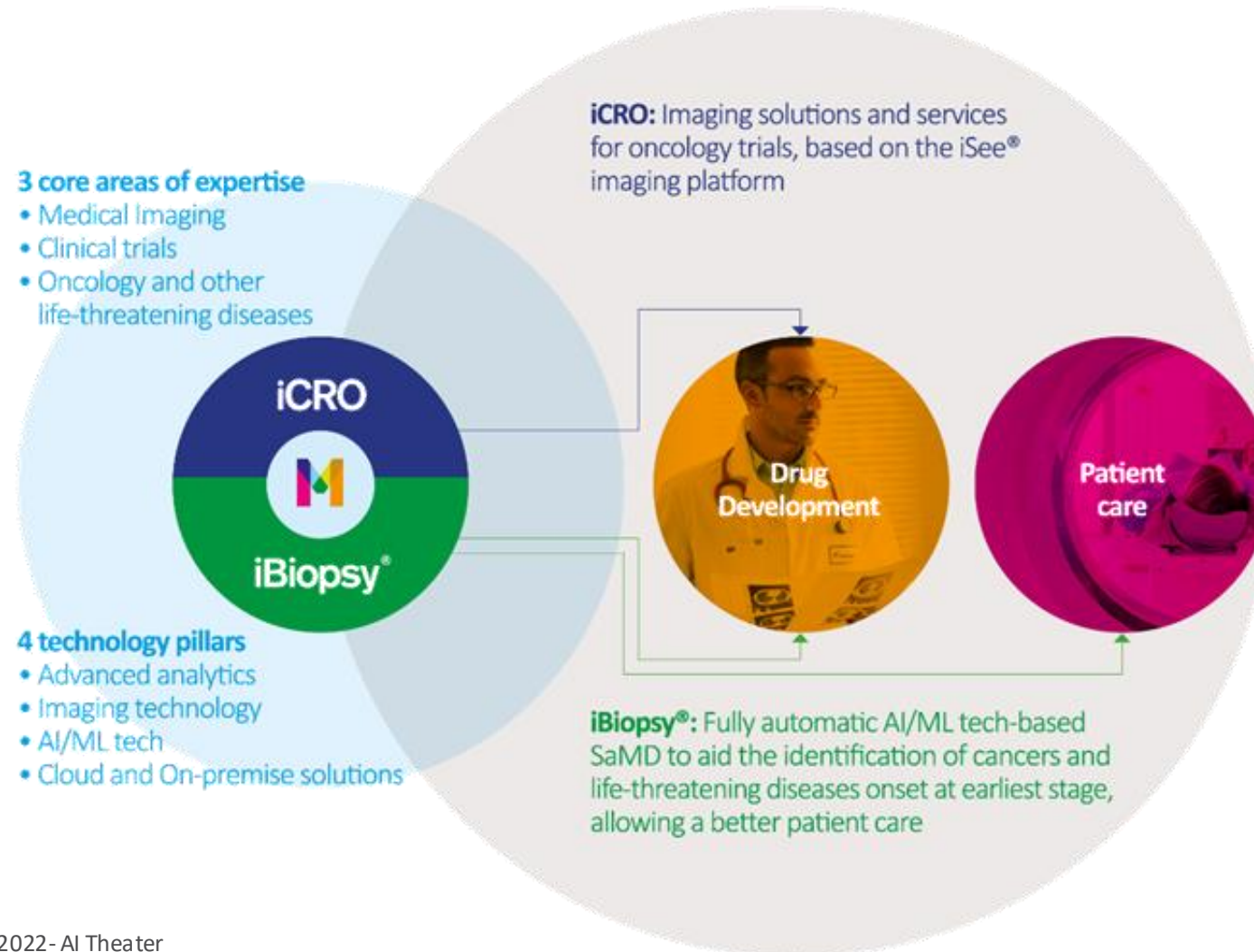
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Median Technologies: Solutions for Disease Diagnosis & Monitoring

Transforming the science of medical imaging



iBiopsy® Platform: Look Beyond What You See



Designing the most advanced AI/ML tech-based SaMD to enhance diagnostic performance & support clinicians to achieve the most accurate diagnosis at the earliest disease onset



The iBiopsy® CAdE/CADx SaMD leverages Median's expertise and capabilities in:

- Medical device & Pharma
- Signal & Image processing
- AI & data science
- Software engineering
- Clinical development
- Regulatory, Marketing, Market access

To:

- Create the next generation of **automatic AI/ML tech-based CAdE/CADx SaMD portfolio**
- Achieve **unprecedented accuracy**
- Decrease **false negative & false positive** results
- **Improve patients lives**
- Reduce **unnecessary procedures** and **healthcare spending**

Our Differentiators

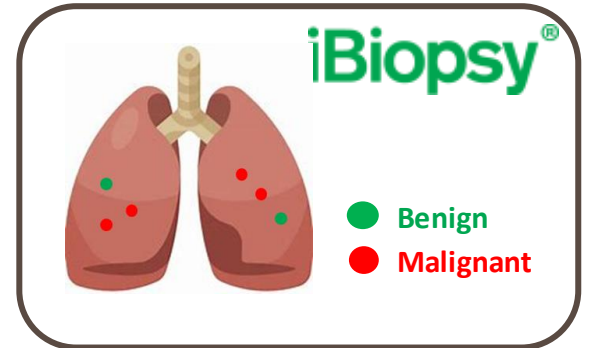
We started developing the CAdE first, followed by the CAdx to create the only fully automatic CAdE/CAdx SaMD



3

CAdE/CAdx: Computer-aided detection & characterization

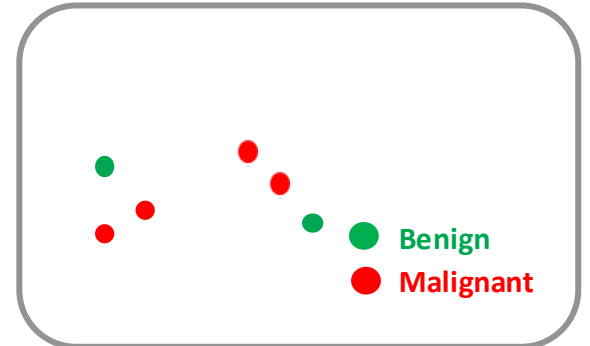
- **Completely automatic** lesion detection and characterization into benign/malignant
- **Better accuracy** for less false negative & false positive results
- **Better patient care due to early diagnosis & treatment**
- **Less healthcare spending due to unnecessary procedures**



2

CAdx: Computer-aided characterization

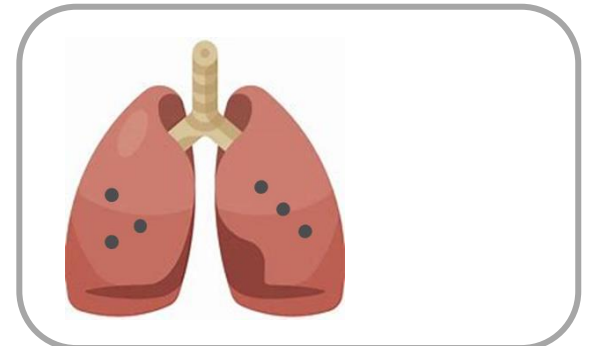
- Automatic lesion characterization into **benign/malignant**
- Higher diagnostic accuracy
- Reduction of false positive & negative results
- Reduction of unnecessary procedures (like biopsies)



1

CAdE: Computer-aided detection

- Automatic organ detection
- Automatic lesion detection & quantification
- Reduction of time to find a lesion
- Increased accuracy



Lung Cancer Screening (LCS)

Facts & Figures



- **1st cancer killer** worldwide - **18%** of all cancer deaths in 2020 [1]
- **1.8M deaths** in 2020, **2.4M** projected in 2030 [1]
- 5-year overall survival rate **18%**, **5%** for distant tumors [2]
- **<25%** cases diagnosed in stage 1 (5-y survival rate: **68%-92%**) [3]
- **>40%** cases diagnosed in stage 4 (5-y survival rate is **<10%**) [3]

Only 870K screenings performed in the US in 2021 – 6% compliance [4]

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

False alarms



Result in additional CTs, bronchoscopies, or biopsies.

Low positive detection rate



Ultimately, only about 5% of scanned people will be diagnosed with lung cancer.

Radiation exposure



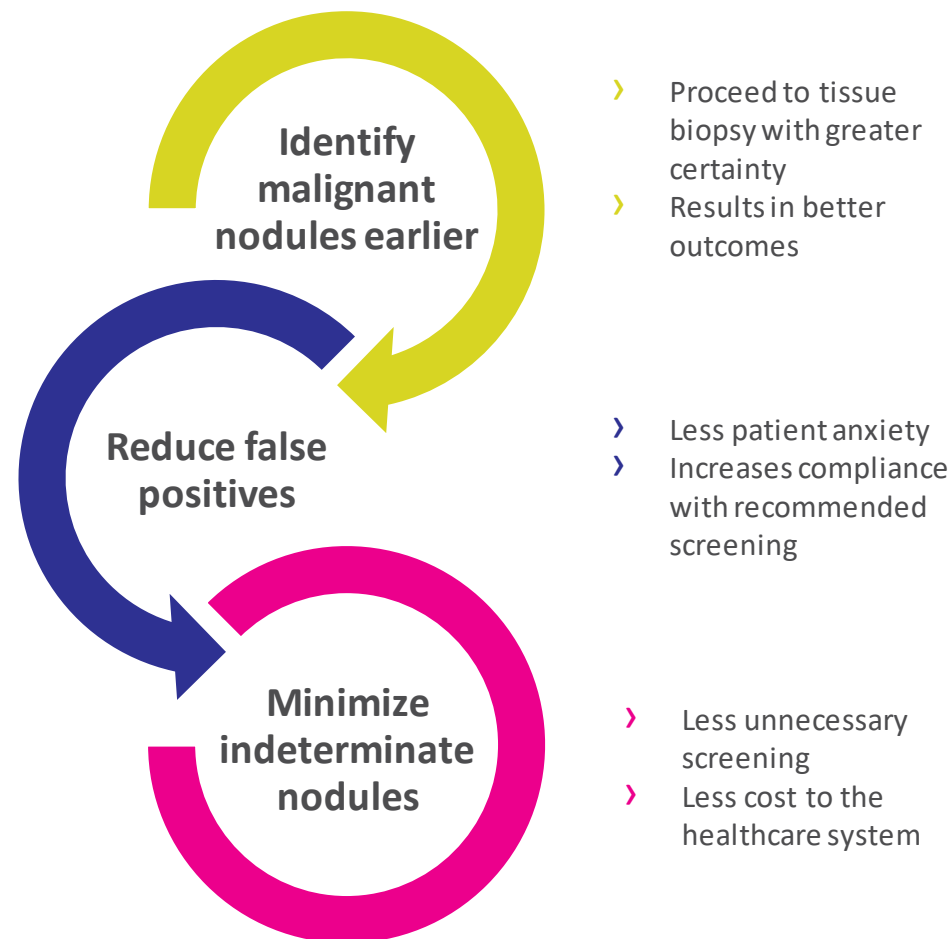
Although the risk is low, there are still negative views against LDCT.

Availability of quality testing



Need trained radiologists for all screening & Many man hours

Our medical device: *iBiopsy*[®] LCS



[1] <https://gco.iarc.fr/>

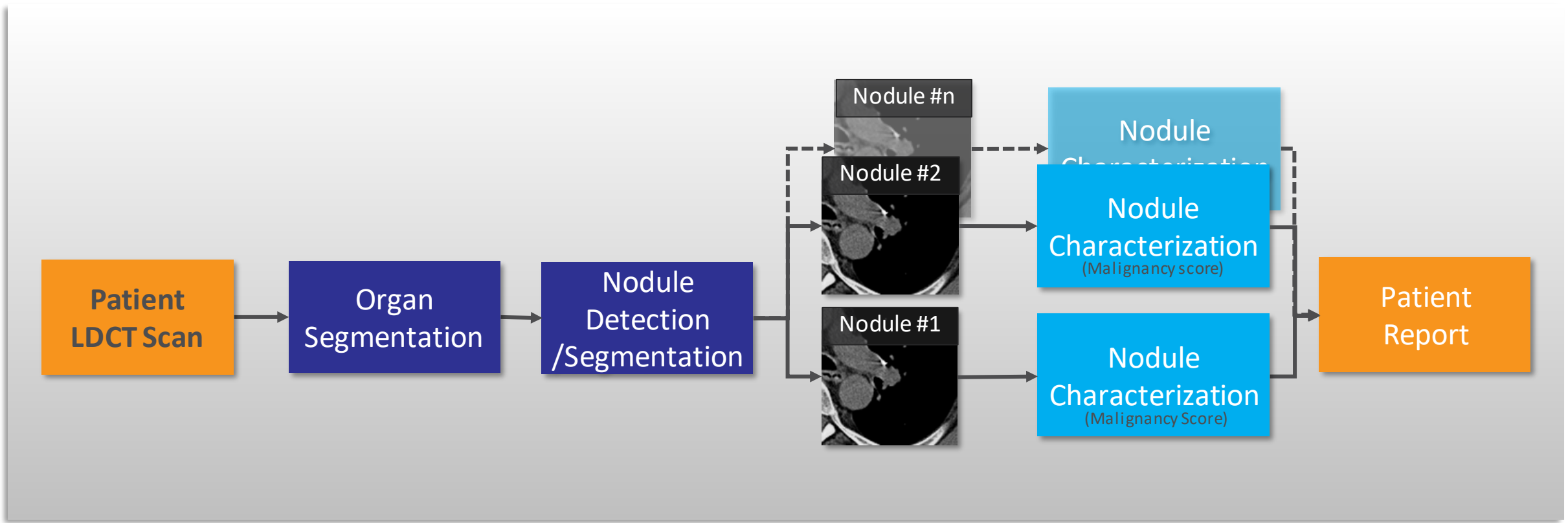
[2] <https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library>

[3] <https://www.lungambitionalliance.com/our-initiatives/lung-cancer-screening-the-cost-of-inaction.html>

[4] <https://nrdsupport.acr.org/support/solutions/articles/11000093991-lcsr-state-reports>

iBiopsy[®] LCS CADe/CADx Processing Methodology

State-of-the-art Artificial Intelligence & Data Science detection segmentation and characterization



iBiopsy[®] LCS Detection Results (CADe)

Automatic lung nodule detection with unprecedented performance

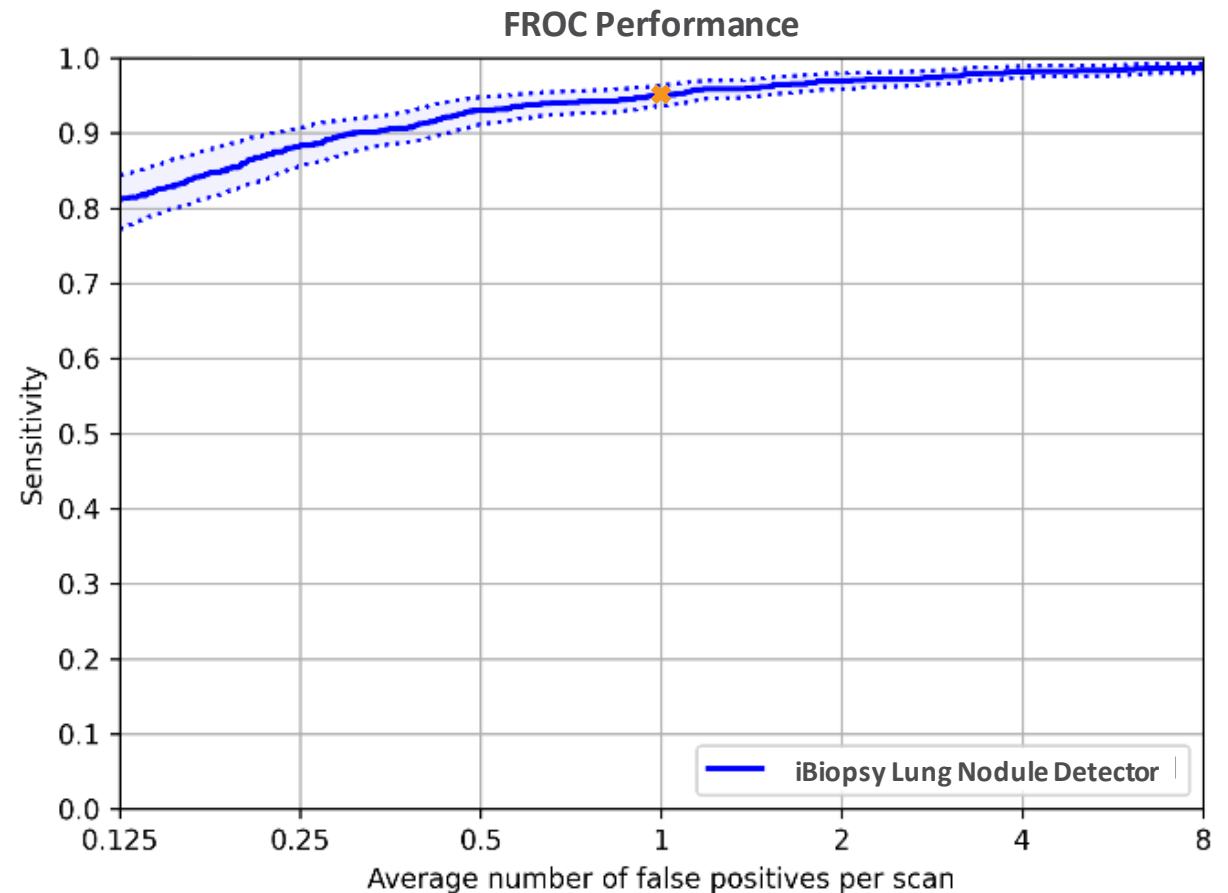
Nodule Detection

LIDC/IDRI Cohort (Luna16 Grand Challenge)

- › Lung CT scans of 888 patients annotated by 4 experienced radiologists for a total of 1,186 nodules
- › Training set: 800 patients
- › Test set: 88 patients
- › Training/testing using 10-fold cross-validation method

Encoder-Decoder Deep Architecture

- › Results: (obtained by aggregating the ten test folds)
- › **Sensitivity of 94.9%**
for a false positive rate of 1 per CT scan.



The best combination of Sens / FP per CT scan, superior to any lung CAdE SaMD currently available

iBiopsy[®] LCS Characterization Results (CADx 1/3)

Automatic lung nodule characterization on all lung cancer stages – unrivalled performance

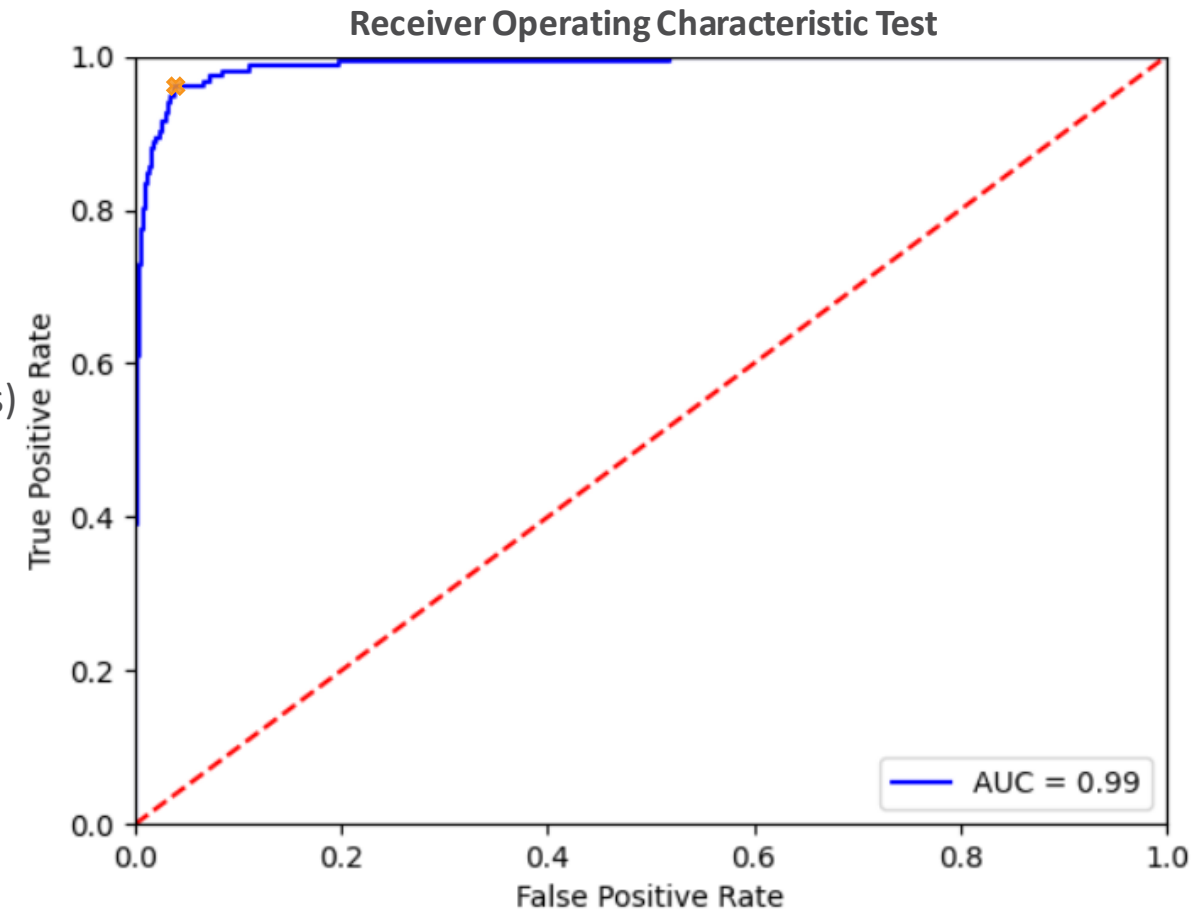
Nodule Characterization

Nodule-wise characterization on NLST sub-set

- › Cohort of 1,737 patients (16,249 nodules)
- › Training set: 1,239 patients (11,676 nodules)
- › Test set: 498 patients [330 benign, 142 malignant] (4,573 nodules)

Deep Architecture with outstanding performance

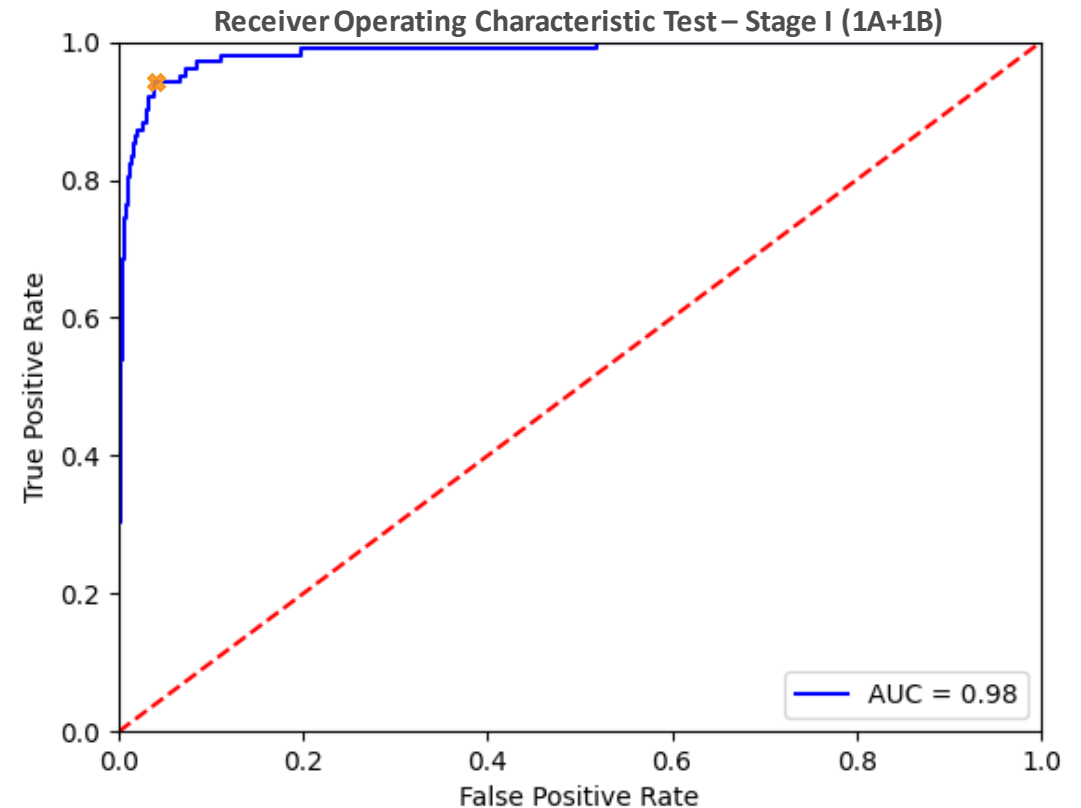
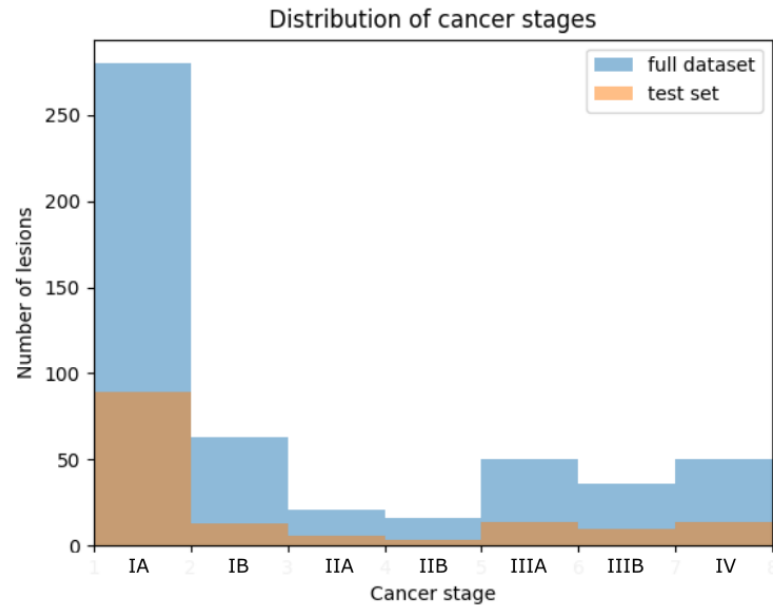
- › **Test AUC = 0.99**
 - Max Youden Index Operating Point ✨:
Sensitivity = 95.3 %, Specificity = 96.2 %



Outstanding KOLs feed-back, unrivalled results, game-changer capacity

iBiopsy[®] LCS Characterization Results (CADx 2/3)

Automatic lung nodule characterization on Stage 1 lung cancer - unprecedented lung cancer characterization performance, beyond the state-of-the-art



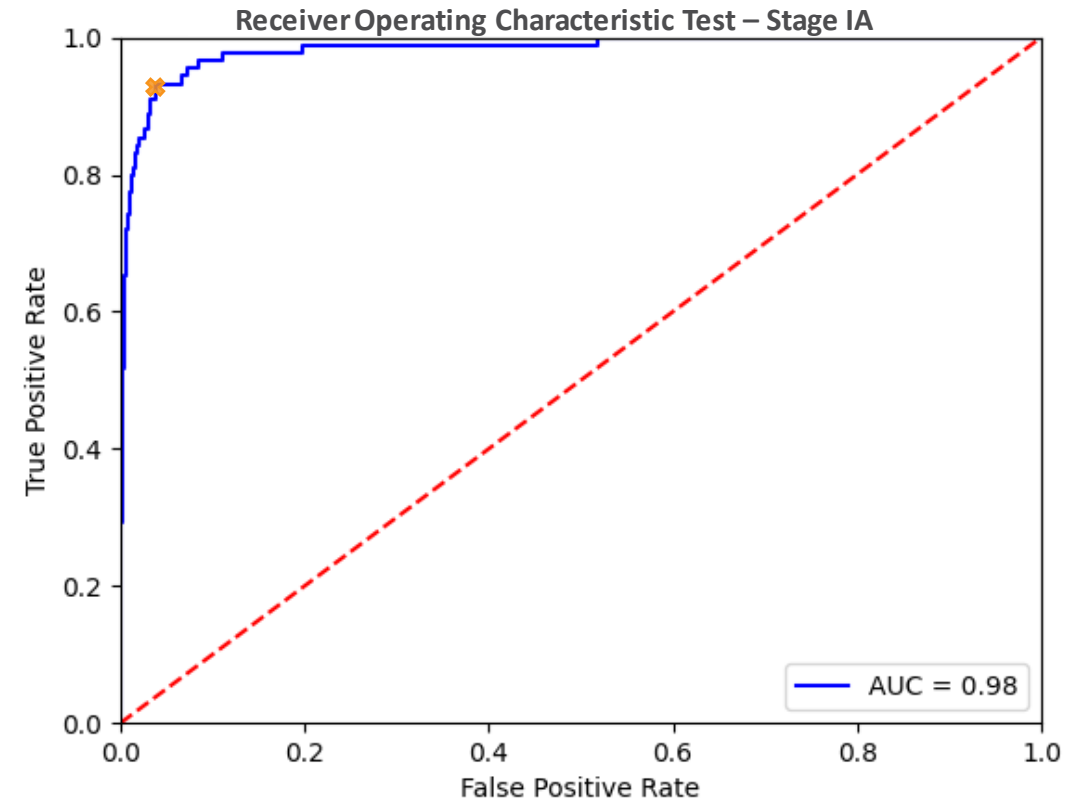
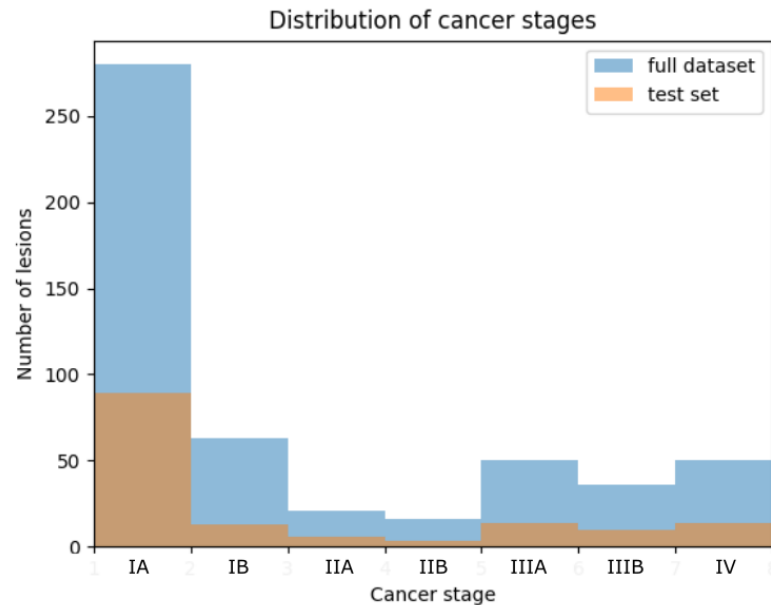
Test AUC = 0.984

- Operating Point ✨:
Sensitivity 93.1% at Specificity 96.2%

Second-to-none ability to identify the earliest onsets of lung cancer

iBiopsy[®] LCS Characterization Results (CADx 3/3)

Automatic lung nodule characterization on Stage 1A lung cancer - Lung Cancer characterized at the earliest onset thanks to our superior accuracy



Test AUC = 0.982

- Operating Point ✨:
Sensitivity 92.1% at Specificity 96.2%

Second-to-none ability to identify the earliest onsets of lung cancer

iBiopsy[®] LCS CADe/CADx End-to-End Results

Automatic lung nodule detection & characterization on all lung cancer stages - our first results confirm our unrivalled accuracy in detecting & characterizing nodules

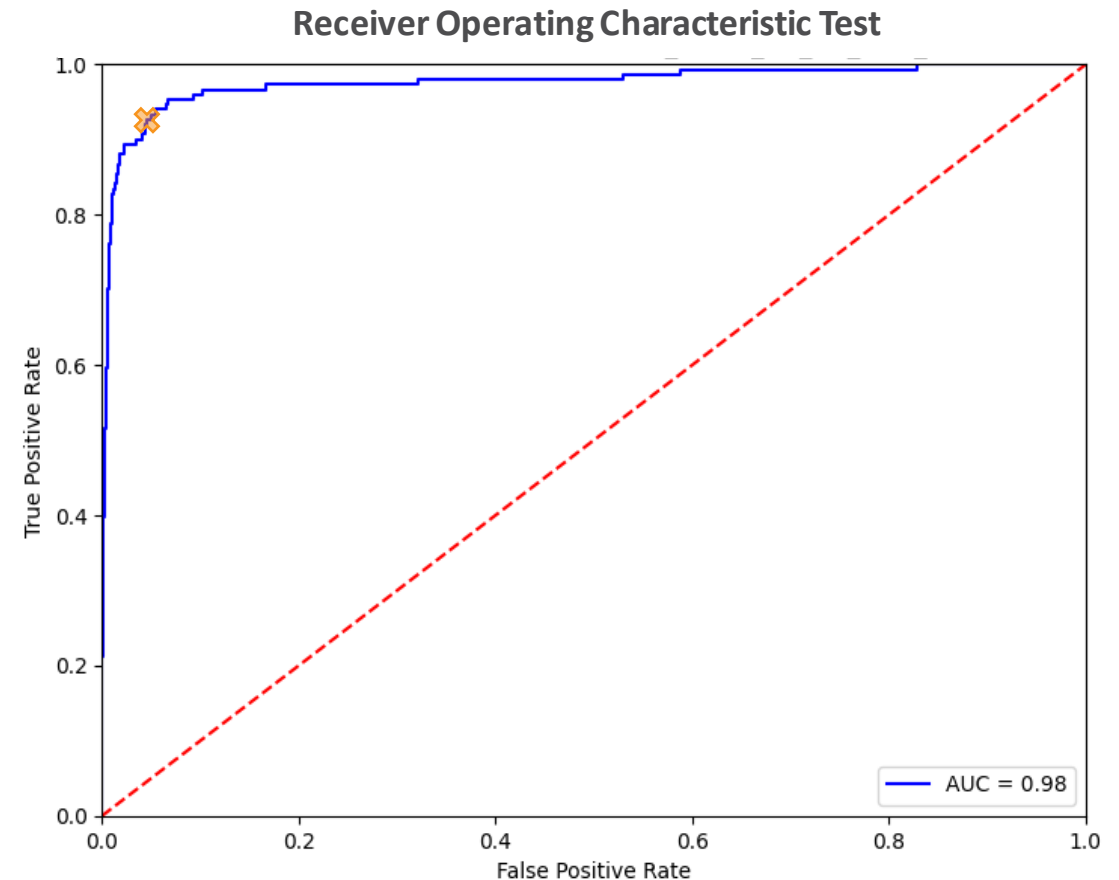
- Automatic Nodule Detection and Characterization

- Cohort: 1,760 NLST patients (16,789 Nodules)
- Test set:
 - › 4,681 nodules (151 malignant, 4,531 benign)
 - › 471 patients (146 malignant, 325 benign)

- Model: Combination of Deep Neural Networks, 3D-Morphological and Radiomics features

- Lesion Level Performance

- **AUC = 0.976**
- Max Youden Index Operating Point✳:
 - Sensitivity = 94.7 %**
 - Specificity = 93.3 %**





iBiopsy[®]



iBiopsy[®] Lung Cancer Screening is an AI-powered software that has demonstrated very promising results, that outperform the state of the art.



iBiopsy[®] LCS benefits:

- End-to-end imaging workflow support,
- Early pulmonary nodules identification leading to early treatment,
- False positive and false negative reduction,
- Unnecessary invasive procedure & healthcare spending reduction.



iBiopsy[®] LCS FDA Pivotal Clinical Trial to start by year's end.



iBiopsy[®] currently focuses on Lung Cancer Screening (LCS), Liver cancer (HCC) very early detection and Non- Alcoholic Steato Hepatitis (NASH) diagnosis and scoring.



For more information,
visit us at Booth
#AI-29, Expo 1, AI area

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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