Development and Validation of a Machine Learning Based CADx Designed to Improve Patient Management in Lung Cancer Screening Programs

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Disclosures

All Authors are employed by: Median Technologies, Valbonne, France

Epidemiology

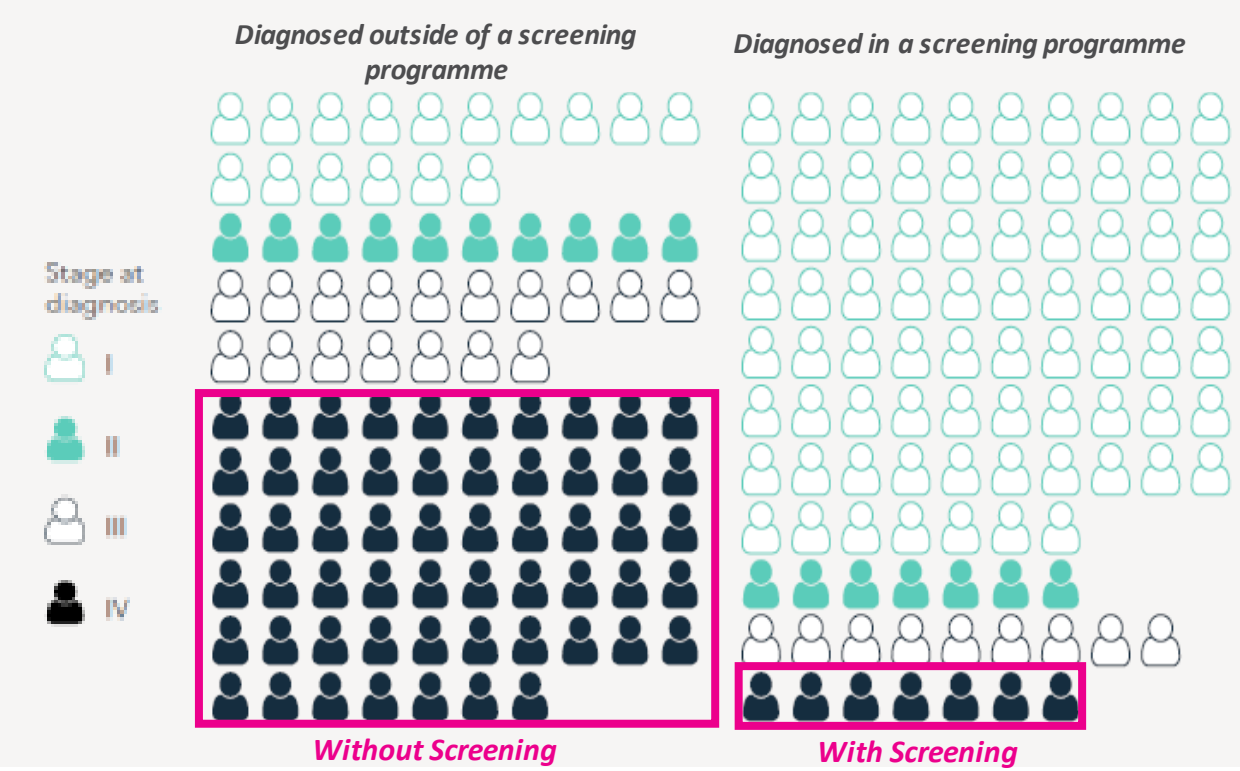
Key points

1. **Mortality:** Lung cancer is the **leading cancer killer worldwide**, accounting for 18% of all cancer deaths
   - A total of **1.8M deaths in 2020 (2.4M in 2030)**
   - **Low 5-year overall survival rate: 18%**
2. **Incidence: 2nd most commonly diagnosed cancer** representing 11.4% of all new cancer cases
   - **2.2M new cases in 2020 (2.9M in 2030)**
3. **Prevalence: 4th among all cancers with 2.6M prevalent cases** (5-year)
4. **More common in men (65%) than women (35%)** - Mortality rates mostly rising among women in many countries due to tobacco use & cessation discrepancy
5. Mostly found in **elderly population**
   - 86% of US cases found in patients >60 years old
   - Average age of people when diagnosed is about 70

Sources:
Sung et. Al (2021): Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries.
Wonget. Al (2017). Incidence and mortality of of lung cancer: Global trends and association with socioeconomic status.

The High Value of LDCT Screening

The NELSON & NLST studies results on LDCT screening



- 20% reduction in mortality among patients who received LDCT vs X-RAY (and ~40% versus no screening)
- A lung cancer detected by LDCT screening will be discovered at an early stage 64% to 85% of the time
  - Early-stage disease is treatable via drug/surgery
  - Comprehensive LDCT Screening – stage IV diagnosis below 15%
    - Without LDCT Screening stage IV ~50%
    - >90% 5 year survival in stage 1

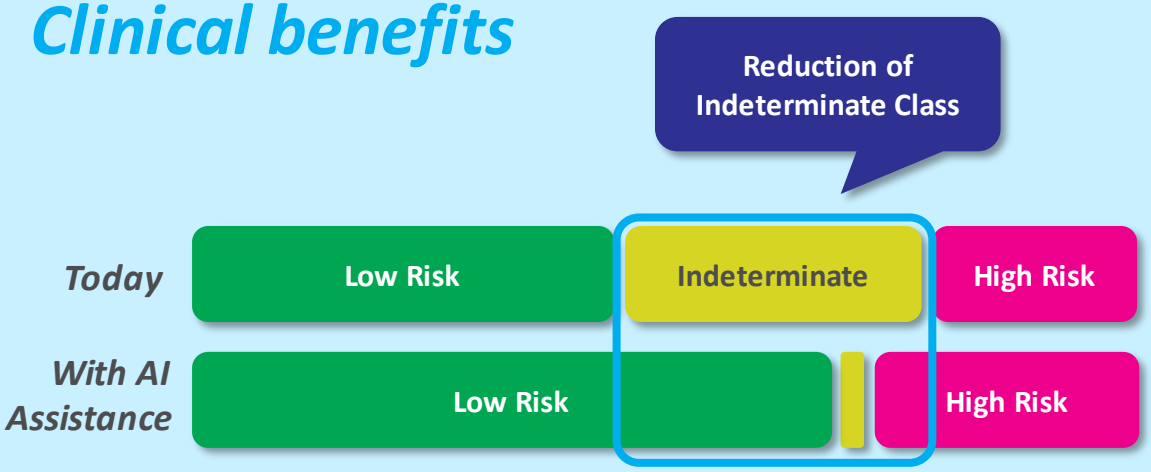
In the USA <7% eligible receive lung screening

Source:
Sands et al (2021). Lung Screening Benefits and Challenges: A Review of The Data and Outline for Implementation.

Unmet Medical Need – Issues With Implementation

- **Radiation exposure:** Although the risk is low, there are still negative views against LDCT.
- **False alarms:** ~25% of LDCT screens resulted in false negatives. Result in additional CTs, bronchoscopies, or biopsies. False alarms can be quite stressful (clinician and patient), and the additional testing can cause harm to the patient.
- **Availability of quality testing:** Important to be screened at a center experienced in lung cancer screening and treatment.
  - Need trained radiologists for all screening
  - Labor intensive
- **Low Screening Penetration**: Low today, but adherence rates increase along with a rise in screening implementation worldwide.

Clinical benefits



Reduce missed cancer (False Negatives)
- Decreases clinicians' anxiety
- Proceed to tissue biopsy with greater certainty

Reduce false positives
- Less unnecessary screening
- Less cost to the healthcare system

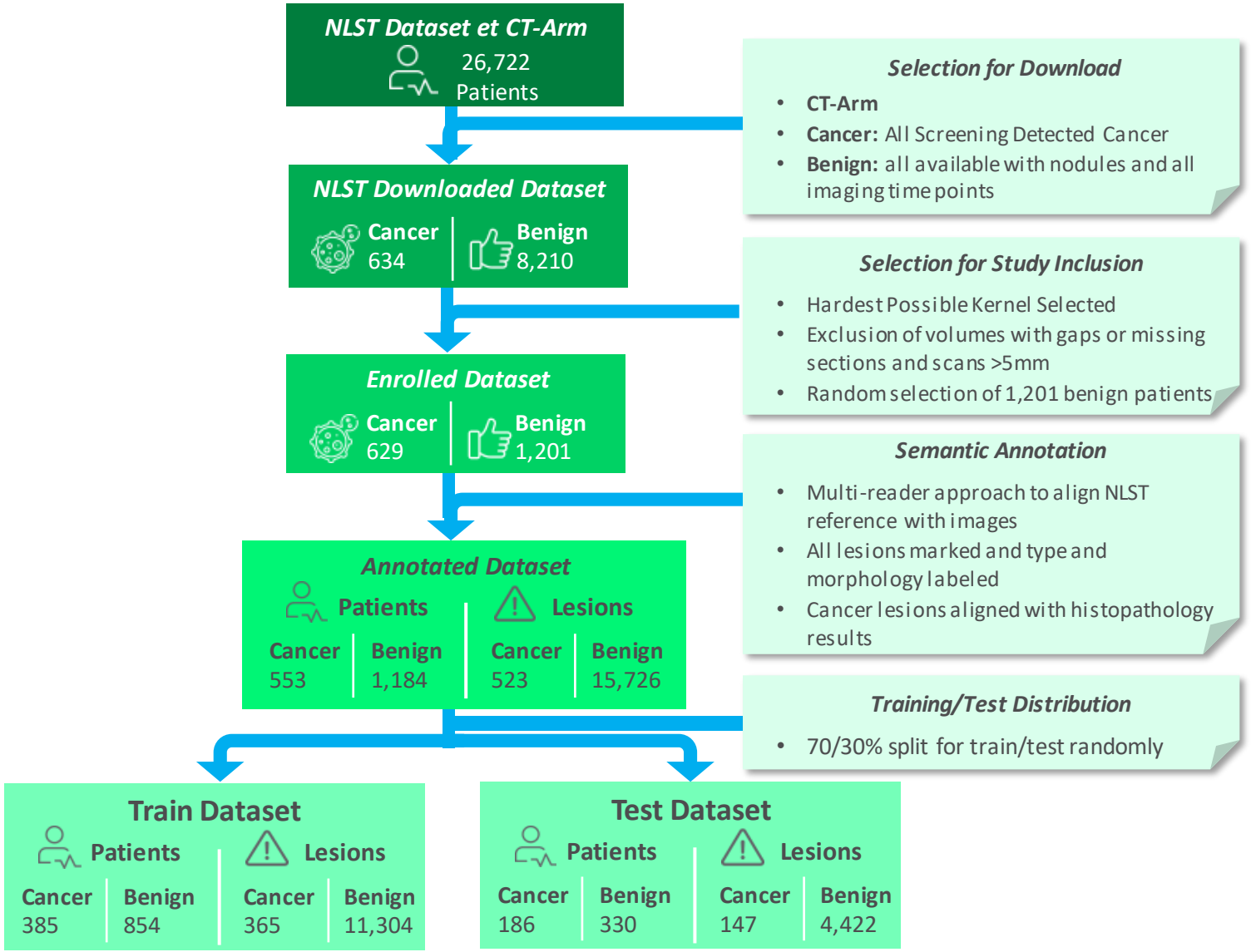
Minimize indeterminate nodules
- Less patient anxiety
- Increases compliance with Lung Screening

Decreased Analysis Time
- Able to scan more patients per year

Sources:
Sands et al (2021). Lung Screening Benefits and Challenges: A Review of The Data and Outline for Implementation.
Lopez-Olivo et. al (2020). Patient Adherence to Screening for Lung Cancer in the US: A Systematic Review and Meta-analysis.

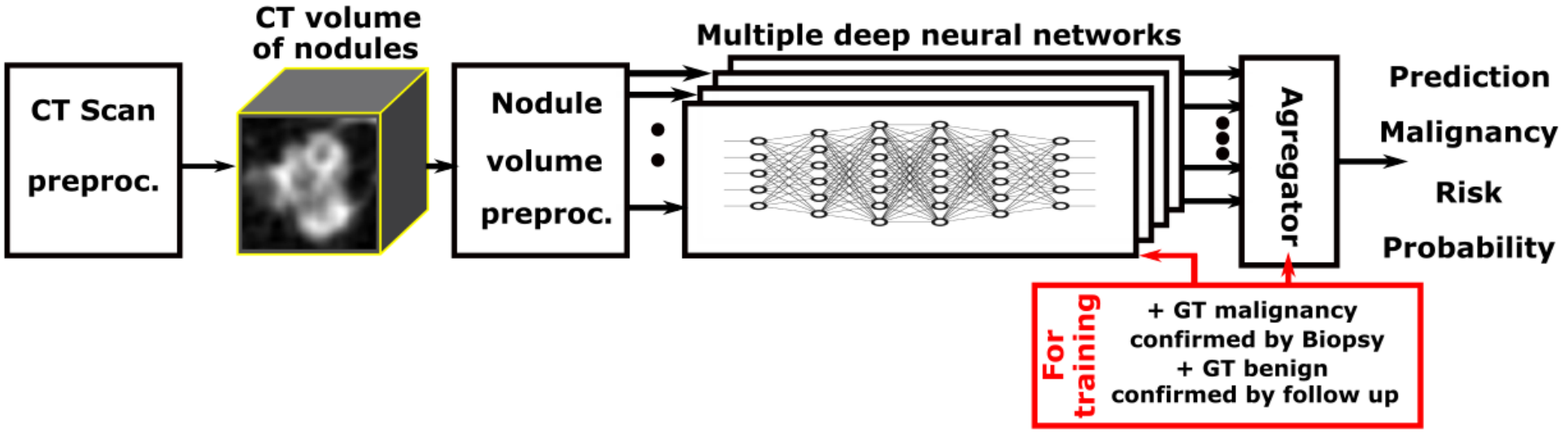
Lung Screening Dataset – NLST trial

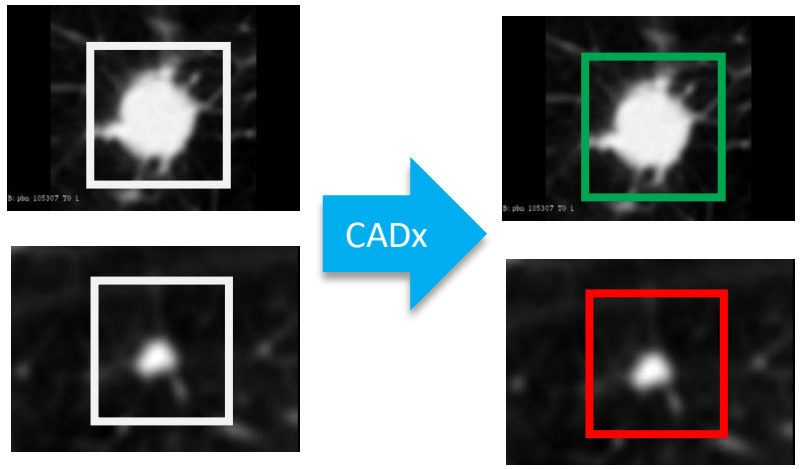
- Patients selected from the NLST Dataset.
- 1,737 patients - 16,249 nodules
- Patients with screen detected cancer (553)
- Benign patients with nodules (1,184)
- 70/30 train-test split
- Lesion annotated and semi-auto segmented by 2 readers



CADx Classifier Model

Key features: Ensembling of very different deep Convolutional Neural Networks





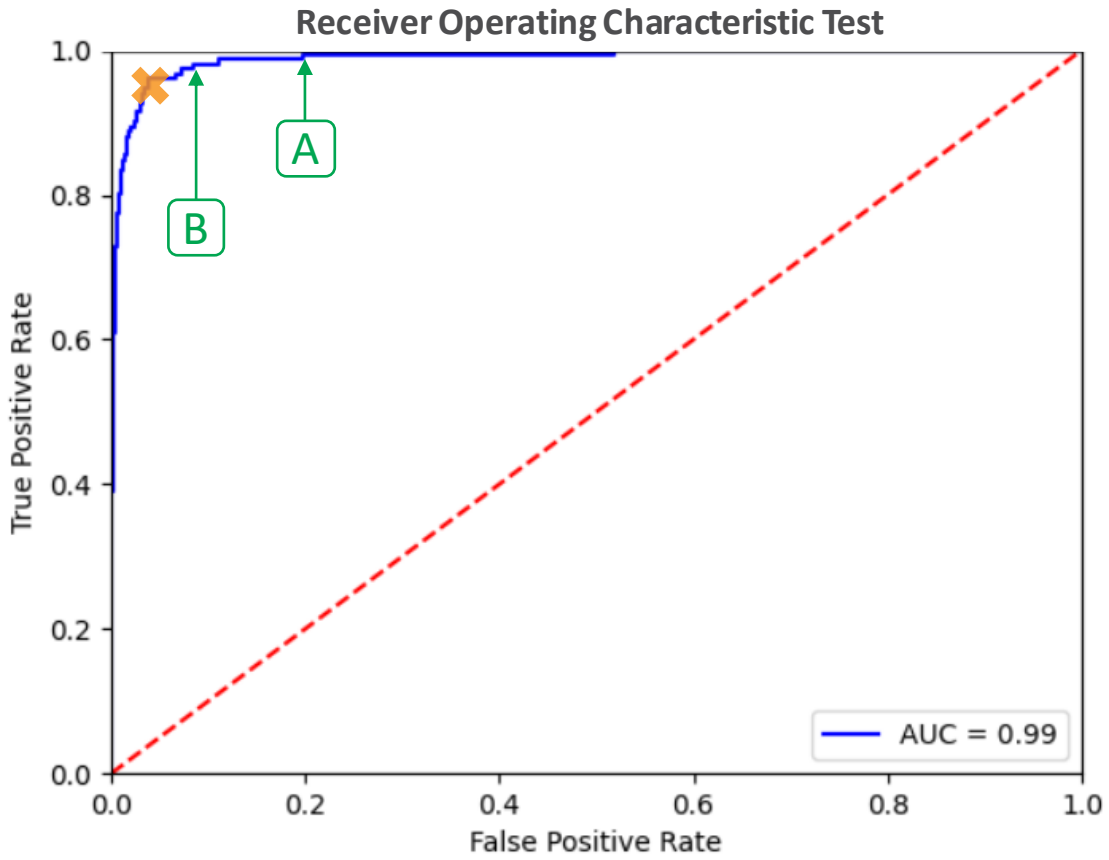
- **Input:** Patch Containing Lesion
- **Output:** Malignancy Prediction Per Patch

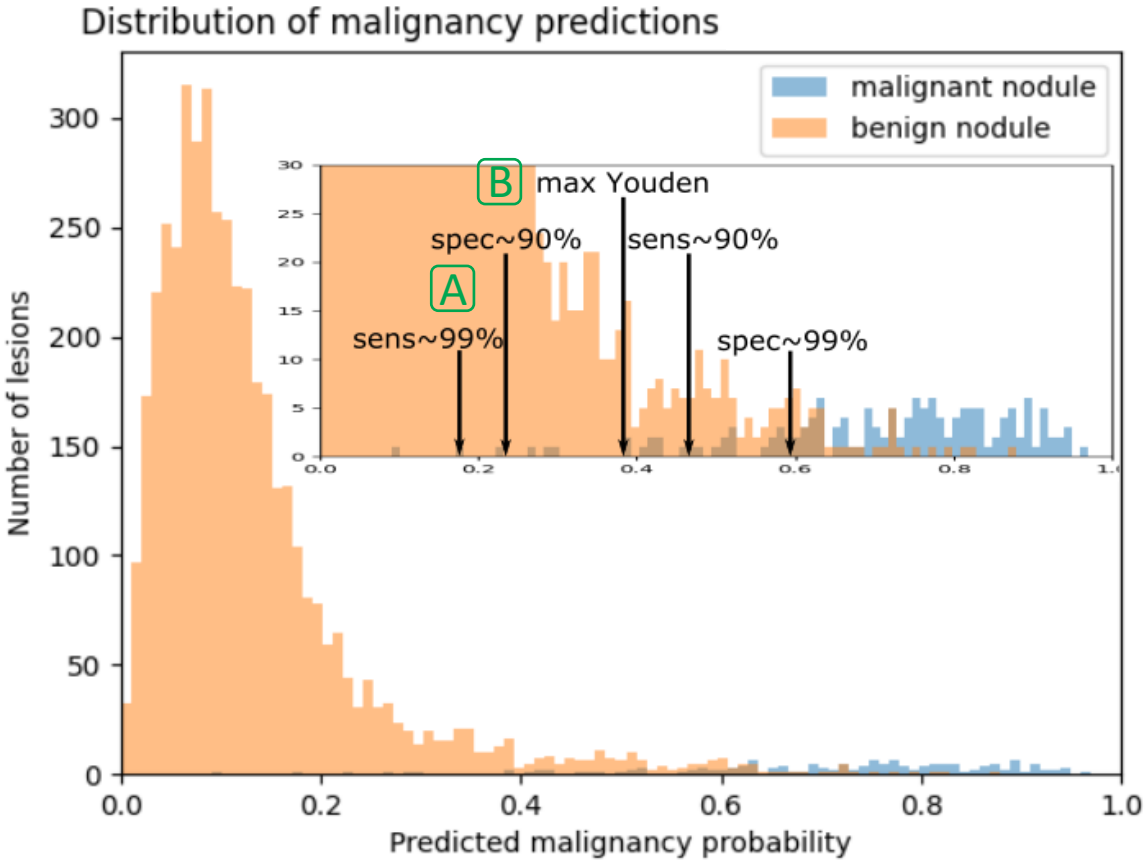
LCS Nodule Characterization Results (CADx)

Automatic lung nodule characterization on all lung cancer stages

› **AUC of ROC on test = 0.99, max Youden Index Operating Point: Sensitivity = 95.3%, Specificity = 96.2%**

- Operating point: Sensitivity 98.6% at Specificity 80.2% A
- Operating point: Sensitivity 97.3% at Specificity 91.4% B

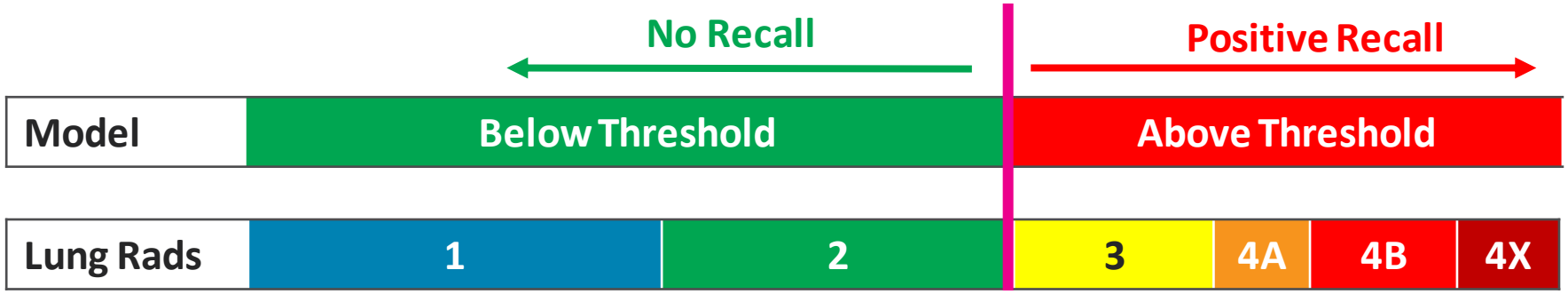




Translation in the wild

Enhancing Patient Recall Rate

- NLST population (2.4% cancer prev), assuming the Lung-Rads performance (Pinsky 2015; 78% Sens, 94% Spec).
- When used in a Recall/No-Recall paradigm compared to Lung-Rads
  - Model (Below threshold no recall, Above Threshold recall)
  - Lung-Rads: (LR1-2 no recall, LR3+ recall)
- Recall/Non (< LR3 / > LR 3)
  - **Saved scans 57% decrease**
  - **Faster scanned cancers (67% increase)**
- When used to assign patient recall, this algorithm could help reduce **unnecessary scans 57%** and **late cancer scans by 67%** compared to using Lung-RADS.



Conclusions and Takeaway Message

AI in Lung Cancer Screening

- The model demonstrates robust performance for the characterization of pulmonary nodules detected by radiologists.
  - 0.991 (95% CI: 0.987-0.995), with 98% sensitivity at a specificity of 90%
- When deployed in a screening program, high performant characterization tools stand to drastically improve patient management.
  - ↓ Unnecessary scans 57%
  - ↓ Late cancer scans by 67%
- With such AI there is the possibility to:
  - ↓ Unnecessary scans and invasive procedures, and
  - ↓ Missed cancers
  - ↓ Reading time, and reader workload
  - ↑ Helps increase screening adherence and implementation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