
# New Non-Invasive Technology For the Early Detection of Cancer At the Cellular Level

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# Biomoda, Inc.

- ***New Mexico cancer diagnostics company that has developed an inexpensive, non-invasive, simple and accurate test for early cancer detection.***

- **Creating innovative tools for disease management (screening tests for cancers):**
  - **Lung**
  - **Cervical**
  - **Colorectal**
  - **Breast**
  - **Prostate**

# Cancer Statistics

- Cancer is the greatest disease killer in the U.S. for individuals under 85 years old
- Net cancer death rate unchanged from 1950 to 2002

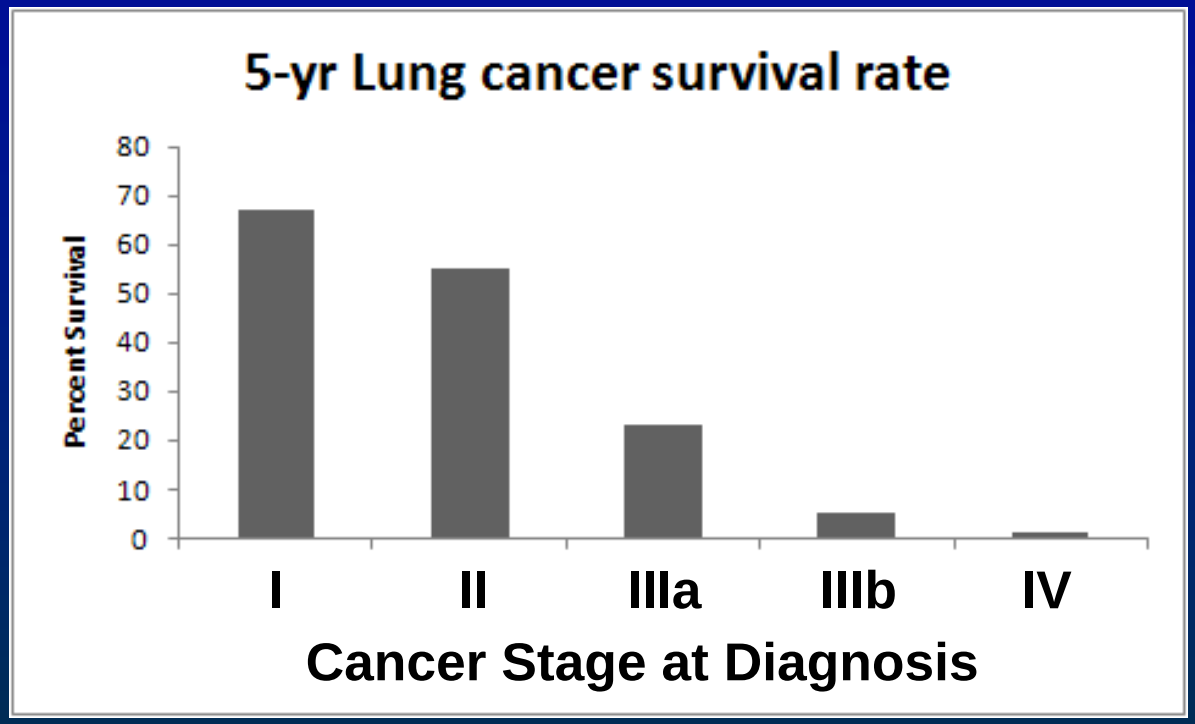
# Lung Cancer

- The leading cause of U.S. cancer deaths
- ~60% of diagnosed patients die within one year

# Lung Cancer (LC)

- 2007: 213,000 Americans diagnosed w/ LC
- 2007: 160,000 Americans died of LC
- LC treatment costs the U. S. $5-6 B/y
  - most expensive form of cancer to treat
- ~95% of LCs are caused by smoking
  - most preventable form of cancer

# Lung Cancer




**ELCAP Study - New England Journal of Medicine (2006)**
**(Early Lung Cancer Action Program)**

**When LC is diagnosed in Stage-1 (tumor is localized), 5-year survivability goes to 67%**

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# National Cancer Institute Lung Cancer Study

## Computed Tomography (CT) vs. X-rays

NCI, National Lung Study Trial web page, 2005

- 7-yr study *comparing chest X-ray to CT* for reducing patient's chance of dying from LC
- 90 million current or former smokers in U.S.
- X-rays detect tumors 1-2 cm in size
- CT detects tumors ≤ 1 cm in size
- At diagnosis LC has metastasized in 15-30% of cases
- However, this study concludes that no scientific evidence to date has shown that screening or early detection of LC actually saves lives

# Survival of Stage-1 Lung Cancer patients detected by CT scan

Henschke, et al., NEJM, 2006

- **Stage-1 LC diagnosed by *annual CT screening*: Patient outcome is unknown**
- **10-year survival rate estimated to be 88%**
- **With surgery within 1 mo. of diagnosis the survival rate was 92%**
- **8 patients with clinical Stage-1 LC who did not receive treatment died within 5 years of diagnosis**
- **CT detected six times more Stage-1 LC than chest x-rays (2.3% vs. 0.4%)**

# Computed Tomography (CT)

Brenner & Hall, NEJM, 2007

- CT has revolutionized diagnostic radiology
- 62 million CT scans in U.S. each year
- CT involves larger radiation doses than X-rays
- Benefit vs. risk is positive for serious conditions
- Low-dose CT (1/2-1/5 of diagnostic CT) can have an adverse impact on image quality
- Therefore, multiple tests may be conducted, increasing radiation dose to patients*
- Authors conclude that U.S. cancer rate from CT scan will increase from 0.4 % to 2 % (a 5-fold increase)

## Need

**Predictive, Inexpensive, Non-invasive Early Stage (0-1) Diagnostic Test(s)**

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# Typical organ radiation doses from various radiologic studies

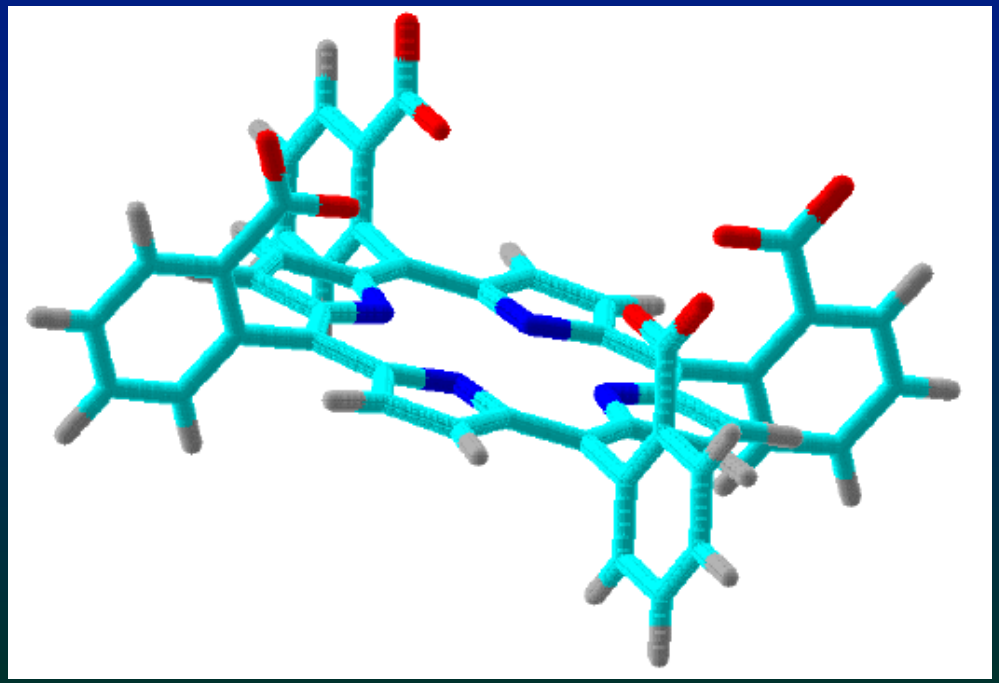
| Study Type | Ref. organ | Organ dose (mGy or mSv) |
|---|---|---|
| PA chest x-ray | Lung | 0.01 |
| Lateral chest x-ray | Lung | 0.15 |
| Adult Abdominal CT | Stomach | 10 (= 1000 PA x-rays) |
| Neonatal Abdominal CT | Stomach | 20 (= 2000 PA x-rays) |

Brenner & Hall, NEJM 2007

# Biomoda Technology Overview

- Onco-labeling Technology
- Cancer cells preferentially absorb TCPP

  5,10,15,20-tetrakis (4-carboxyphenyl) porphine



- Fluoresces red when excited by UV light

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# Initial TCPP Study

## Fluorescence Index (FI) from Uranium miners

### LANL / St. Mary's Hospital

| Cancer | # patients | FI Index |
|---|---|---|
| Squamous cell | 5 | 83.5 |
| Adenocarcinoma | 1 | 68.0 |
| Small cell carcinoma | 3 | 42.7 |
| Metastatic Lymphoma | 1 | >150.0 |
| Non-cancerous | 4 | 15.2 |

**In this blinded study**

**Specificity = 100% and Sensitivity = 100%**

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# TCPP Assay Protocol

- Patients cough up sputum into fixative cup
  - either self-induced, induced by saline spray, or Lung Flute
- Sputum sample is prepared on microscope slide
- Slide sample is soaked in assay solution
- Slide is “read” under microscope with UV/Blue light source

(Flow cytometry studies are beginning)

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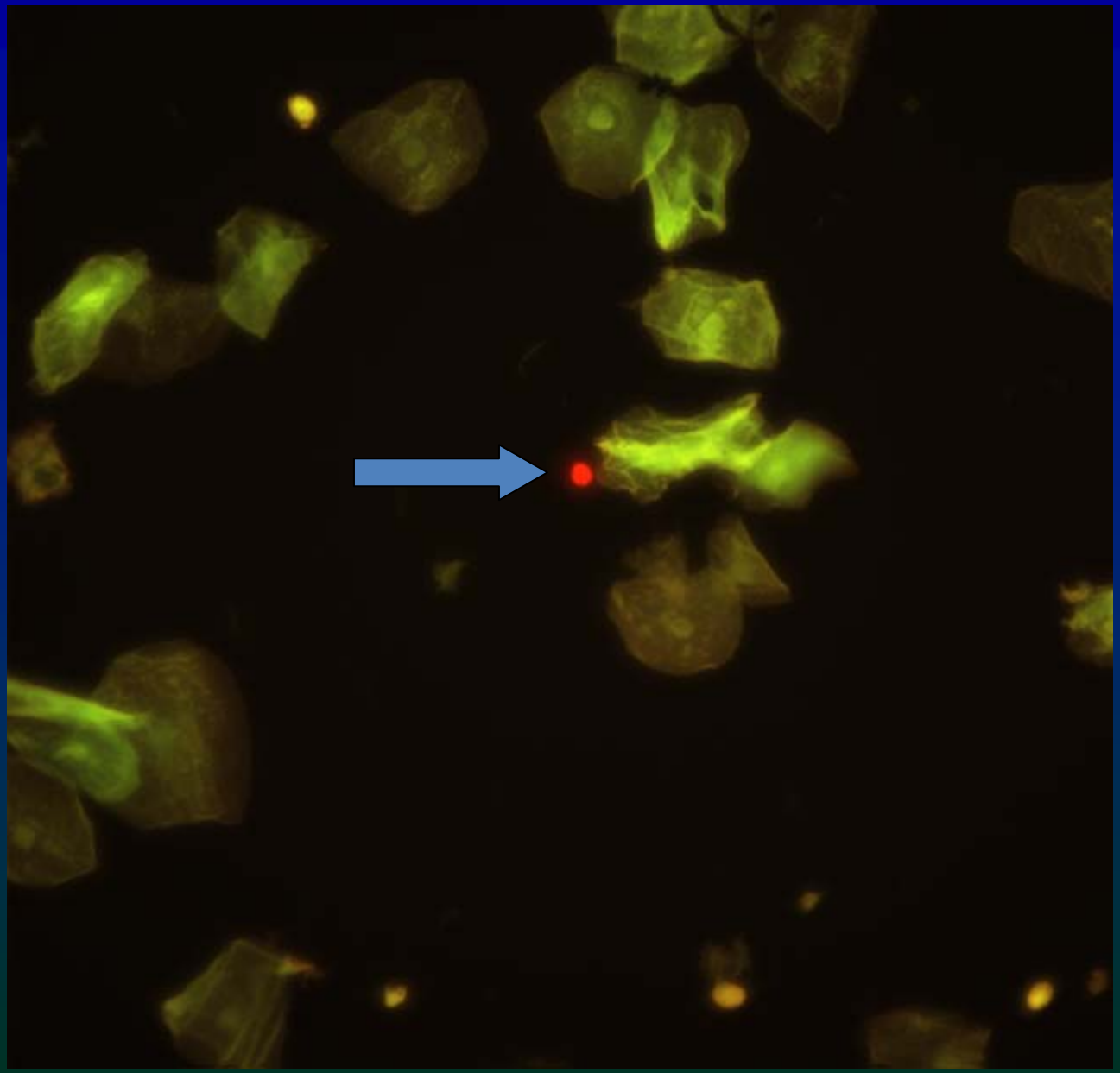

Tumor cell glows red under fluorescent light

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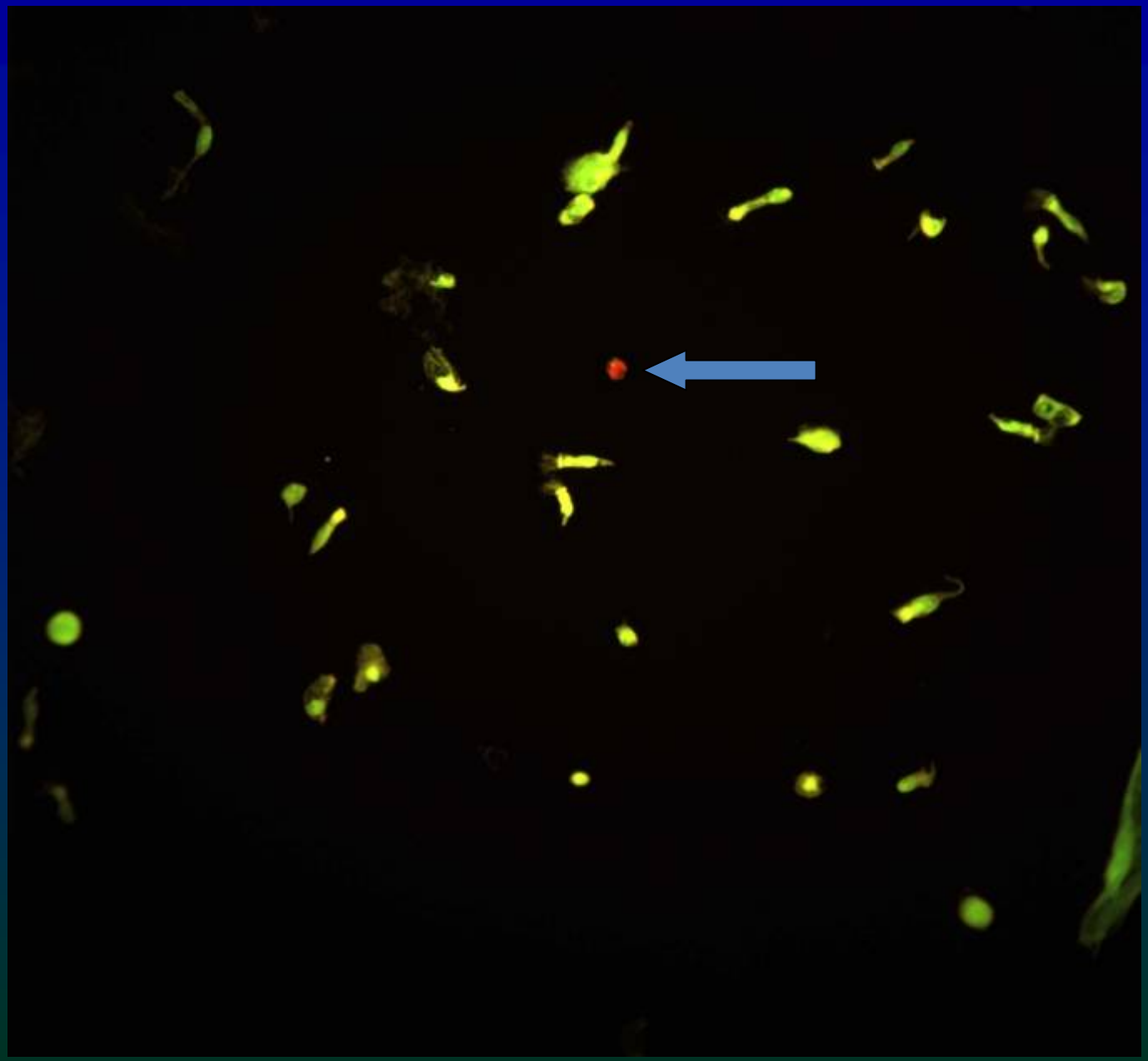

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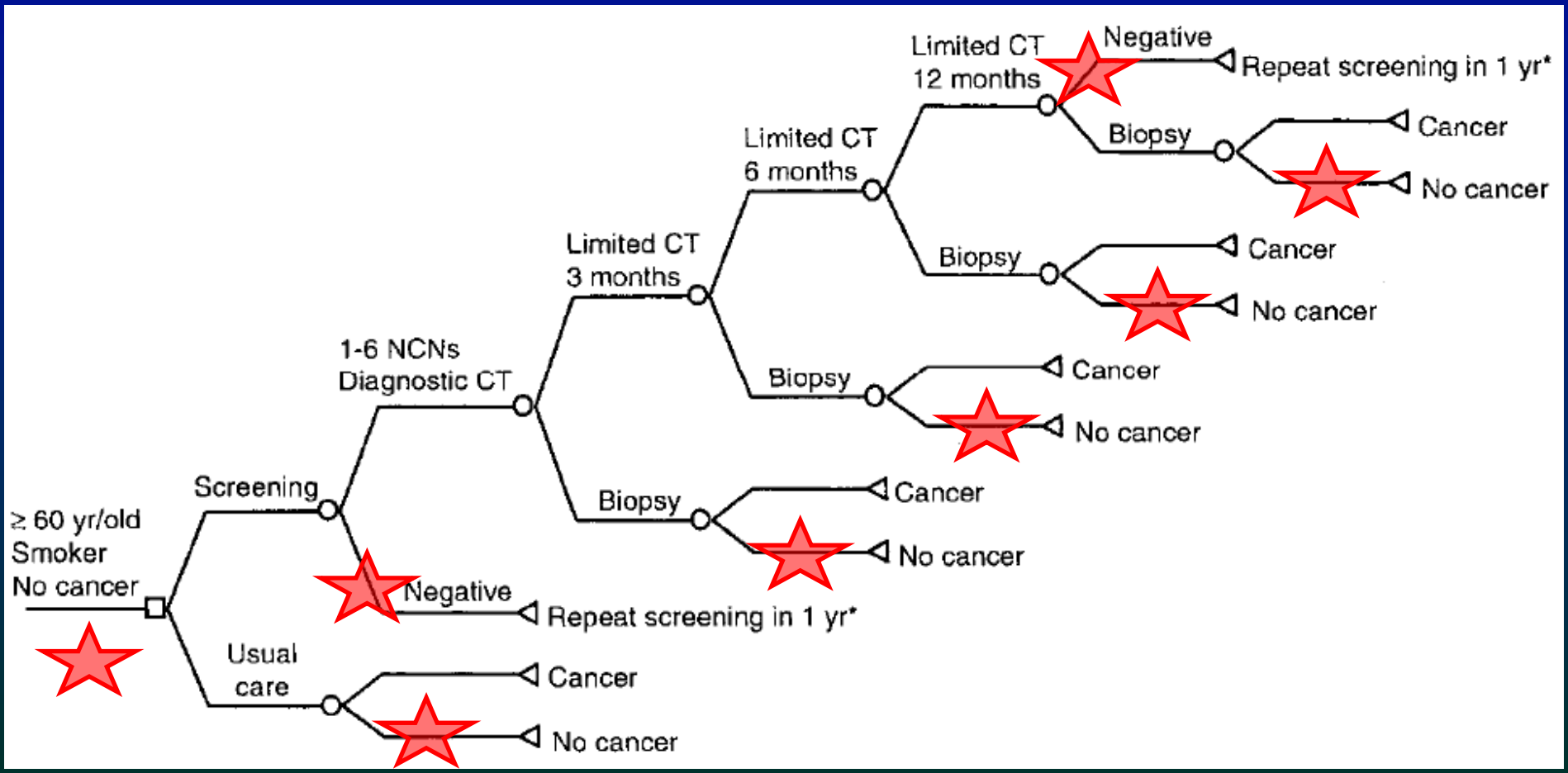
# ELCAP Study Protocol




- Proposed Biomoda Assay Integration into ELCAP Protocol

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# Clinical Study of Veterans to Detect Early Lung Cancer

- New Mexico Legislature appropriated $1.65M to Biomoda/New Mexico Tech for a clinical study of New Mexico veterans
- Non-invasive sputum test allowing +/- result and large-scale screening
- Expanded clinical team being assembled for TCPP LC study

  (UNM, VA, other New Mexico Hospitals)

# Intellectual Property Overview

## TCPP

### 5,10,15,20-tetrakis (4-carboxyphenyl) porphine

- Granted Patents
  - 1 Licensed from LANL
  - 1 owned by Biomoda
- In Progress
  - 1 CIP Application
  - 1 Divisional Application
- Two Provisional Patent Applications
- PCT protection in 16 countries

**Biomoda seeks to collaborate with researchers and clinicians at U.S. and international institutions to further research and initiate clinical trials for lung & other cancers that are potential candidates for early detection with Biomoda's TCPP technology.**


# Thank you.