Poster# 2228

FIRSTLUNG (L301): Cluster Randomized Trial Evaluating the Clinical Utility of DELFI's Blood-Based Lung Cancer Screening Test

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BACKGROUND

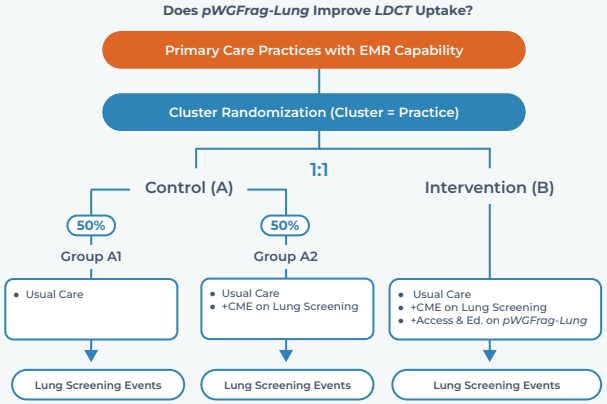
- Low-dose computed tomography (LDCT) has been shown to improve lung cancer detection and reduce mortality. Despite the known benefits and proven effectiveness of screening, uptake in the United States remains low.
- Common barriers to lung cancer screening are multifactorial and occur at the patient, provider, and health system level.
- Uptake of lung cancer screening is likely to improve when different screening modalities are offered. Research suggests patient preference for accessible, convenient options over more invasive modalities (e.g., FIT vs. Colonoscopy) and preference for a blood draw vs. imaging.
- There is a need for alternative non-invasive methodologies to improve the uptake of lung cancer screening with LDCT.
- FIRSTLUNG 301 (NCT06145750) clinical utility study is a prospective, cluster randomized controlled trial (RCT) to observe the impact of a blood-based genomic screening test (pWGFrag-Lung, FirstLook) on lung cancer screening utilization by clinicians in primary care practices and is intended to inform clinical guidelines and policies focused on improving patient care and health outcomes.

METHODS

- Practices will be randomized 1:1 into two arms:
  Arm A (Control) + Arm B (Intervention)
- Arm A practices will be further randomized 1:1 into two groups A1 (usual care) and A2 (usual care + CME on lung cancer screening).
- Arm B practices will have education on and access to the pWGFrag-Lung in addition to a CME on lung cancer screening.
- The primary study endpoint is the proportion of practice-identified lung cancer screen-eligible individuals receiving a screening LDCT during the study period in the entirety of Arm A (Control) versus Arm B (Intervention).
- Time Frame: 15 months

PROGRESS:

The study was initiated in October 2023 with practice randomization. As of September 2024, the study is targeting practice recruitment in 9 states. The study currently includes approximately 13,000 screen-eligibles. The study is on target for primary completion in December 2025.



LUNG CANCER STATE STATISTICS

State	Lung Cancer Deaths[1]	Smoking Rate[1]	Lung Cancer Screen Rate[2]
Arizona	13,171	14.9%	1.3%
Colorado	8,324	13.5%	2.6%
Florida	47,035	14.8%	2.4%
Kansas	5,512	16.2%	7.0%
Massachusetts	12,436	12.0%	11.9%
Michigan	21,032	18.7%	7.1%
Nevada	5,420	15.7%	1.4%
North Carolina	20,409	18.5%	7.1%
Texas	43,403	14.7%	1.2%

#1. www.cdc.gov #2. www.lung.org

CRITERIA

Inclusion Criteria:

1. Practice offers primary care services. Practices may include, but are not limited to: community health centers, academic outpatient facilities, private practices of family or general internal medicine, and Veterans Administration outpatient primary care clinics.
2. Practice has a minimum of 50 individuals who: A. Meet lung cancer screening eligibility criteria as defined by the 2021 USPSTF guideline recommendations (individuals 50-80 years of age, 20 pack-year or more smoking history, currently smoke or quit within the last 15 years) B. Have undergone a clinic visit in the past 12 months, and C. Have not had a CT for lung cancer screening in the last 15 months.
3. Practice can complete electronic medical record data extraction and electronic data capture entry during the study.
4. Practice scores a 4 (agree) or 5 (strongly agree) on a 5-point Likert scale for physical and insurance benefit access to LDCT.
5. Practice can identify a central phlebotomy site.

Exclusion Criteria:

1. Practice is currently participating in other DELFI lung studies.
2. Practice is participating in any other cancer screening blood-based biomarker studies which includes return of results.

OUTCOME MEASURES

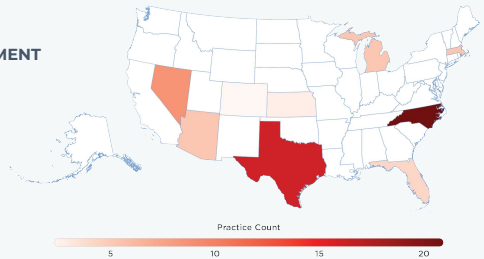
Primary Outcome Measure:

Proportion of practice-identified lung cancer screen-eligible individuals receiving a screening CT order and scan during the study period in each arm.

Secondary Outcome Measures:

1. Proportion of practice-identified screen-eligible individuals receiving a LDCT order and scan for lung cancer screening following *pWGFrag-Lung* "Elevated" and "Not-Elevated" test results during the study period.
2. Estimate the number needed to screen with *pWGFrag-Lung* to detect one additional lung cancer during the study period.

L301 RECRUITMENT BY STATE



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