

RATIONALE:

Lung Cancer Screening (LCS) with Low-dose computed tomography (LDCT) effectively reduces mortality through early detection,^{1,2} yet real-world implementation encounters substantial barriers.^{3,4} Patient adherence challenges and workflow complexities significantly diminish screening benefits at the population level.⁴ To address these limitations, we implemented DELFI FirstLook Lung (FLL),⁵ a blood-based screening test, as a complementary pathway.

METHODS

Key aspects of the implementation beginning October 2024:

- Full integration within our electronic health record (EHR) system.
 - Ordering/reporting capabilities
 - Decision support tools
- Automated eligibility prompts
- Established payor partnerships for reimbursement coverage
- Standardized documentation templates
- Protocols for subsequent LDCT scheduling when clinically indicated
- Deployment of targeted outreach strategies including patient navigator support
- Specifically targeting USPSTF LCS screen eligible patients⁶ who historically resisted or remained unengaged with conventional LDCT programs.

KEY RESULTS

October 2024 through November 2025, 2532 screening eligible patients within the insurance coverage plan were identified through automated eligibility prompts or identified by physicians. We processed 434 eligible patients with FLL orders with 341 patients completing testing (78.5% completion rate) in a population of moderate to high social vulnerability with mean age 60.4 ± 5.9 years.

Notably, of patients receiving FLL results, 214 patients (63.9%) had never received LDCT screening, while 86 patients (25.7%) were over 15 months from their last LDCT, (300/335, 90% collectively) representing meaningful expansion of screening access.

Among completed tests, 144 (42.2%) returned elevated results triggering LDCT referral protocols. Care coordination proved effective, with 139 patients (96.5%) patients receiving LDCT orders and 106 (73.6%) completing imaging studies.

Mean turnaround time from FLL order through blood collection to result decreased from 26.8 ± 35.2 days initially to 19.1 ± 13.6 days by quarter four – a 28.7% reduction.

Clinic-based collection initially outperformed laboratory collection, informing workflow refinements that substantially narrowed this gap.

- REFERENCES:**
1. "Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening". The NLST Research Team. N Engl J Med 2011;365:395-409. VOL. 365 NO. 5
 2. "Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial". Harry J. de Koning, M.D. et al. N Engl J Med 2020;382:503-513. VOL. 382 NO. 6
 3. American Lung Association. State of Lung Cancer 2025 Report.
 4. "Understanding patient barriers and facilitators to uptake of lung screening using low dose computed tomography: a mixed methods scoping review of the current literature" Cavers et al; Respiratory Research volume 23: 374 (2022)
 5. "Clinical Validation of a Cell-Free DNA Fragmentome Assay for Augmentation of Lung Cancer Early Detection". Mazzone et al Cancer Discov. 2024 Jun 6;14(11):2224–2242.
 6. US Preventive Services Task Force (USPSTF). "Screening for Lung Cancer: US Preventive Services Task Force Recommendation Statement." JAMA. 2021;325(9):962–970.
 7. "Performance of Lung-RADS in the National Lung Screening Trial" Pinsky PF, et al. (2015) - JAMA Internal Medicine

***DISCLAIMER**
The FirstLook Lung test is a laboratory-developed test. This test was developed, and its performance characteristics were determined by DELFI Diagnostics. It has not been cleared or approved by the US Food and Drug Administration (FDA). The laboratory is regulated under the Clinical Laboratory Improvement Act (CLIA) as qualified to perform high-complexity clinical tests. The test is used for clinical purposes. It should not be regarded as investigational or for research.*

Figure 1: Patient Testing Workflow

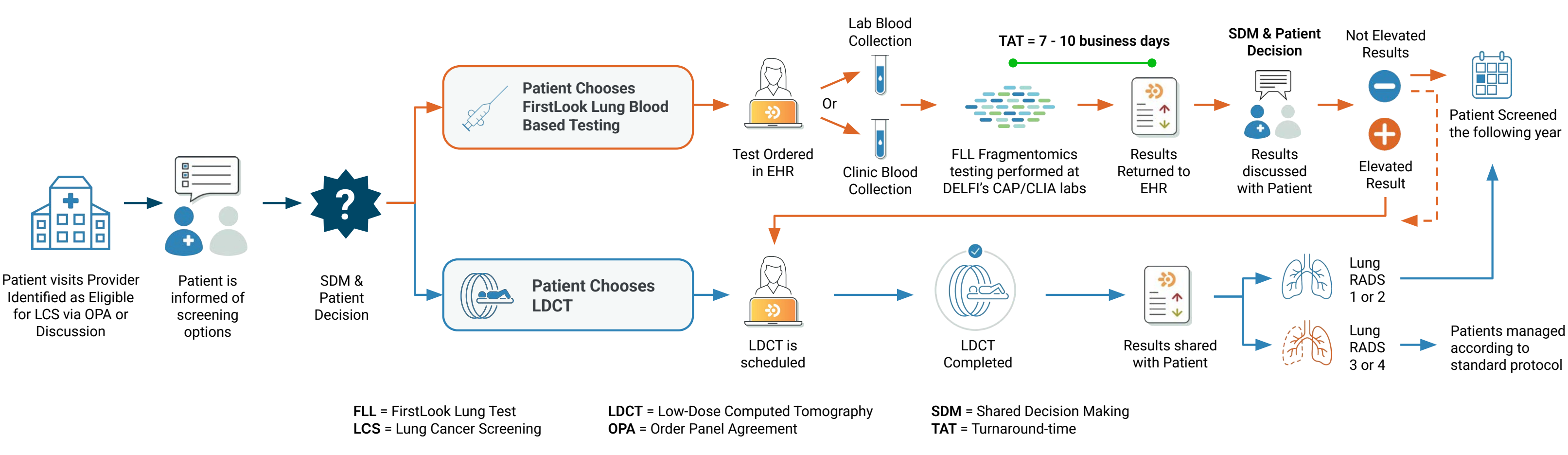


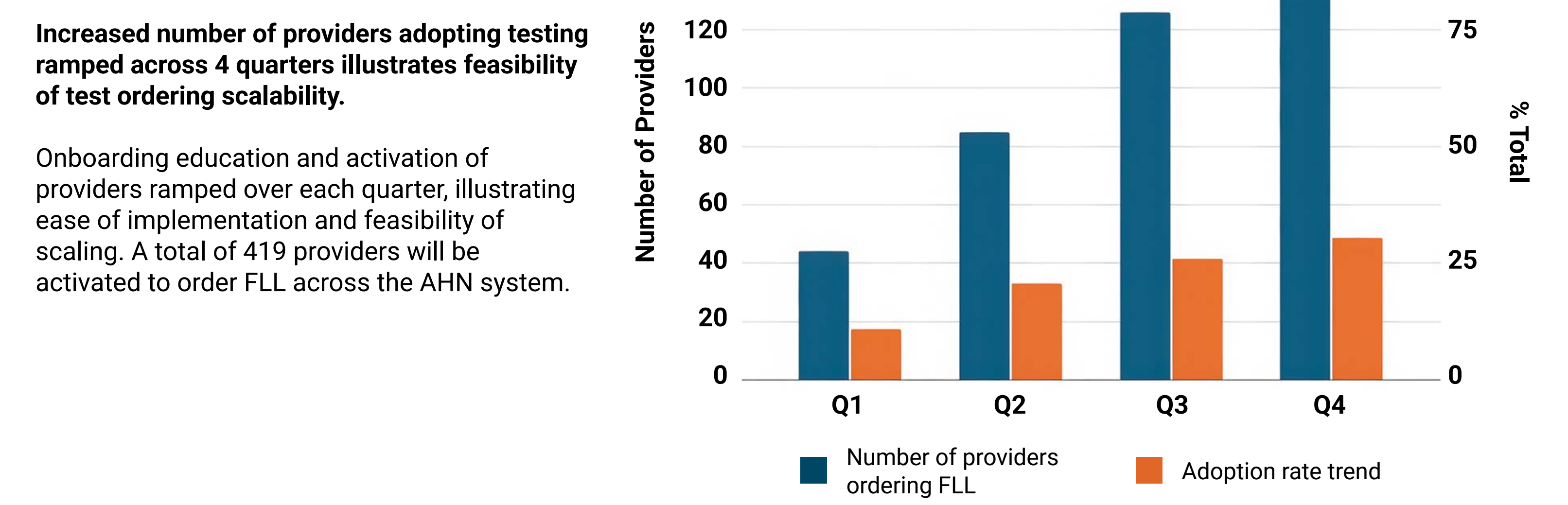
Table 1: Demographics Across the Eligible Population Within Insurance Coverage Plan Invited for Screening With Results

(from Oct 2024 through end Nov 2025; with complete demographic information in EHR)

- Primary Care is an appropriate delivery method to connect patient to Lung Cancer Screening with FLL Testing
- Patients choosing FLL were slightly older, more rural and with a higher percentage of current smokers compared to those choosing LDCT alone.

	Patients choosing FLL with Results (N=335)	Patients choosing LDCT Only with results (N=893)	No LCS (N=1304)	p value
Age	60.4 ± 5.9	59.9 ± 4.7	59.2 ± 4.9	<0.001
Sex				
Male	157 (46.9%)	386 (43.2%)	556 (42.6%)	0.376
Female	178 (53.1%)	507 (56.8%)	748 (57.4%)	
Race				
White	321 (95.8%)	819 (91.7%)	1200 (92.0%)	0.069
Black	13 (3.9%)	53 (5.9%)	71 (5.4%)	
Other/Declined	1 (0.3%)	21 (2.4%)	33 (2.5%)	
Ethnicity				
Hispanic or Latino	2 (0.6%)	2 (0.2%)	13 (1.0%)	0.870
Not Hispanic or Latino	326 (97.3%)	873 (97.8%)	1271 (97.5%)	
Declined	7 (2.1%)	18 (2.0%)	20 (1.5%)	
Smoking Status				
Current	181 (54.0%)	412 (46.1%)	755 (57.9%)	<0.001
Former	154 (46.0%)	481 (53.9%)	549 (42.1%)	
Pack years	35.5 ± 16.4	36.3 ± 16.4	34.0 ± 15.3	0.003
Residence				
Rural	20 (6.0%)	47 (5.3%)	42 (3.2%)	0.021
Suburban	24 (7.2%)	24 (2.7%)	56 (4.3%)	
Urban	303 (90.5%)	822 (92.1%)	1205 (92.5%)	
Social Vulnerability Index				
Low vulnerability	34 (10.2%)	96 (10.8%)	140 (10.7%)	0.207
Low-moderate vulnerability	113 (33.7%)	275 (30.8%)	403 (30.9%)	
Moderate-high vulnerability	135 (40.3%)	338 (37.9%)	544 (41.7%)	
High Vulnerability	54 (15.8%)	184 (20.6%)	217 (16.6%)	
History of cancer (>3 years)	17 (5.1%)	50 (5.6%)	54 (4.1%)	0.279
Comorbidities				
Pulmonary disease	152 (45.4%)	512 (57.3%)	541 (41.5%)	<0.001
Myocardial infarction	23 (6.9%)	74 (8.3%)	112 (8.6%)	0.592
Diabetes mellitus	207 (61.8%)	584 (65.4%)	800 (61.4%)	0.142
Hypertension	228 (68.1%)	574 (64.3%)	835 (64.0%)	0.372
Peripheral vascular disease	44 (13.1%)	105 (11.8%)	158 (12.1%)	0.805
Cerebrovascular disease	39 (11.6%)	120 (13.4%)	146 (11.2%)	0.276
Congestive heart failure	21 (6.3%)	69 (7.7%)	82 (6.3%)	0.387
Specialty				
Primary Care	313 (93.4%)	748 (83.8%)	1227 (94.1%)	<0.001
Pulmonology	15 (4.5%)	129 (14.5%)	54 (4.1%)	
Medical Oncology	7 (2.1%)	16 (1.8%)	23 (1.8%)	

Figure 2: Provider Adoption of FLL Test Ordering by Quarter

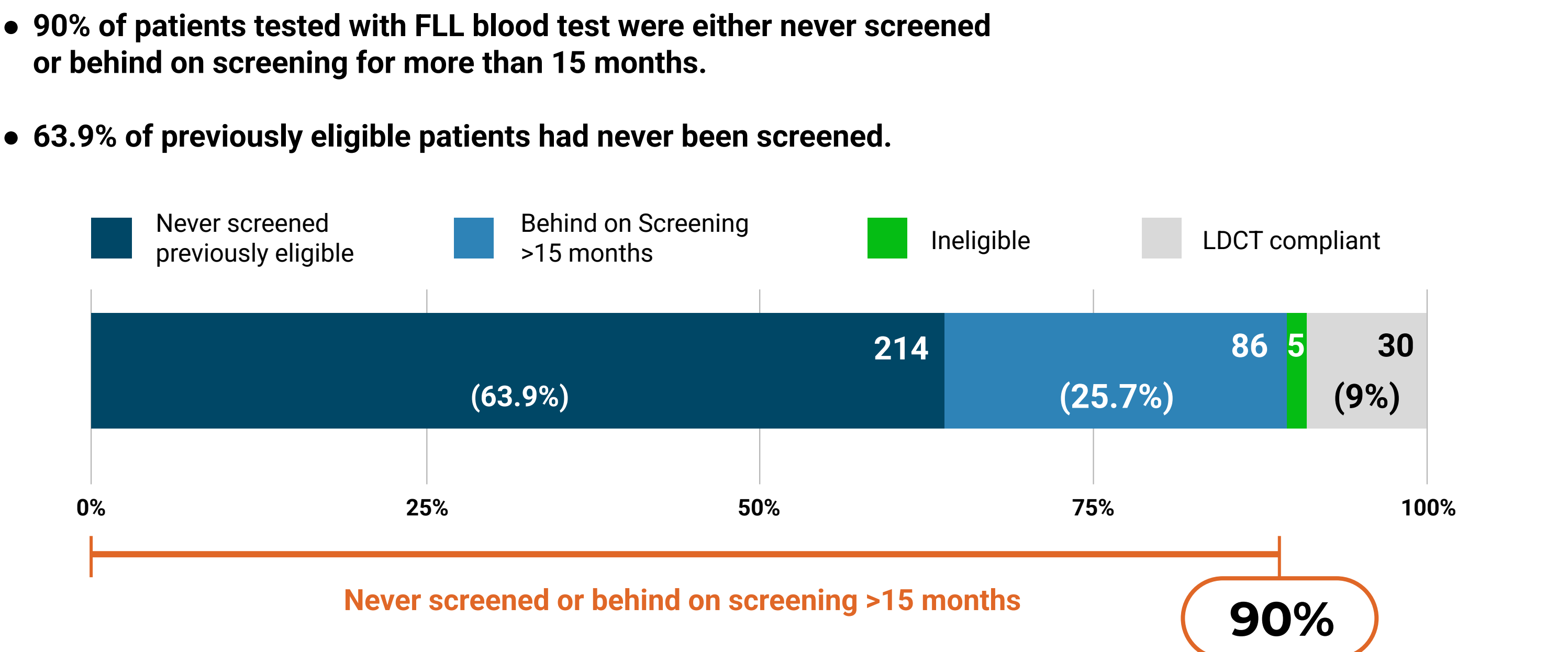


Increased number of providers adopting testing ramped across 4 quarters illustrates feasibility of test ordering scalability.

Onboarding education and activation of providers ramped over each quarter, illustrating ease of implementation and feasibility of scaling. A total of 419 providers will be activated to order FLL across the AHN system.

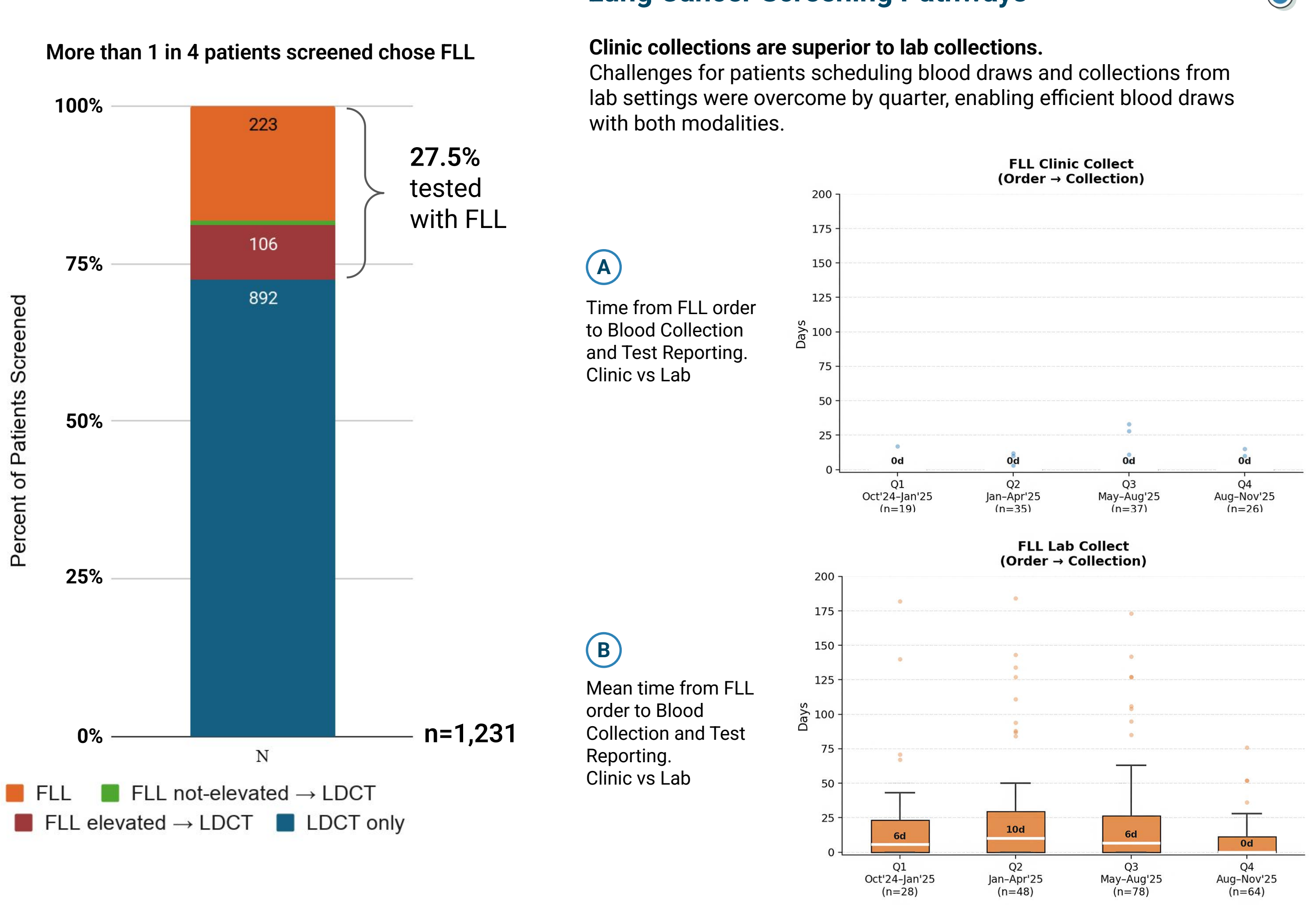
Figure 3: Previous LDCT Screening Status for Patients Within the Payor Plan Tested With the FirstLook Lung Blood Test

n=335 tests reported



- 90% of patients tested with FLL blood test were either never screened or behind on screening for more than 15 months.
- 63.9% of previously eligible patients had never been screened.

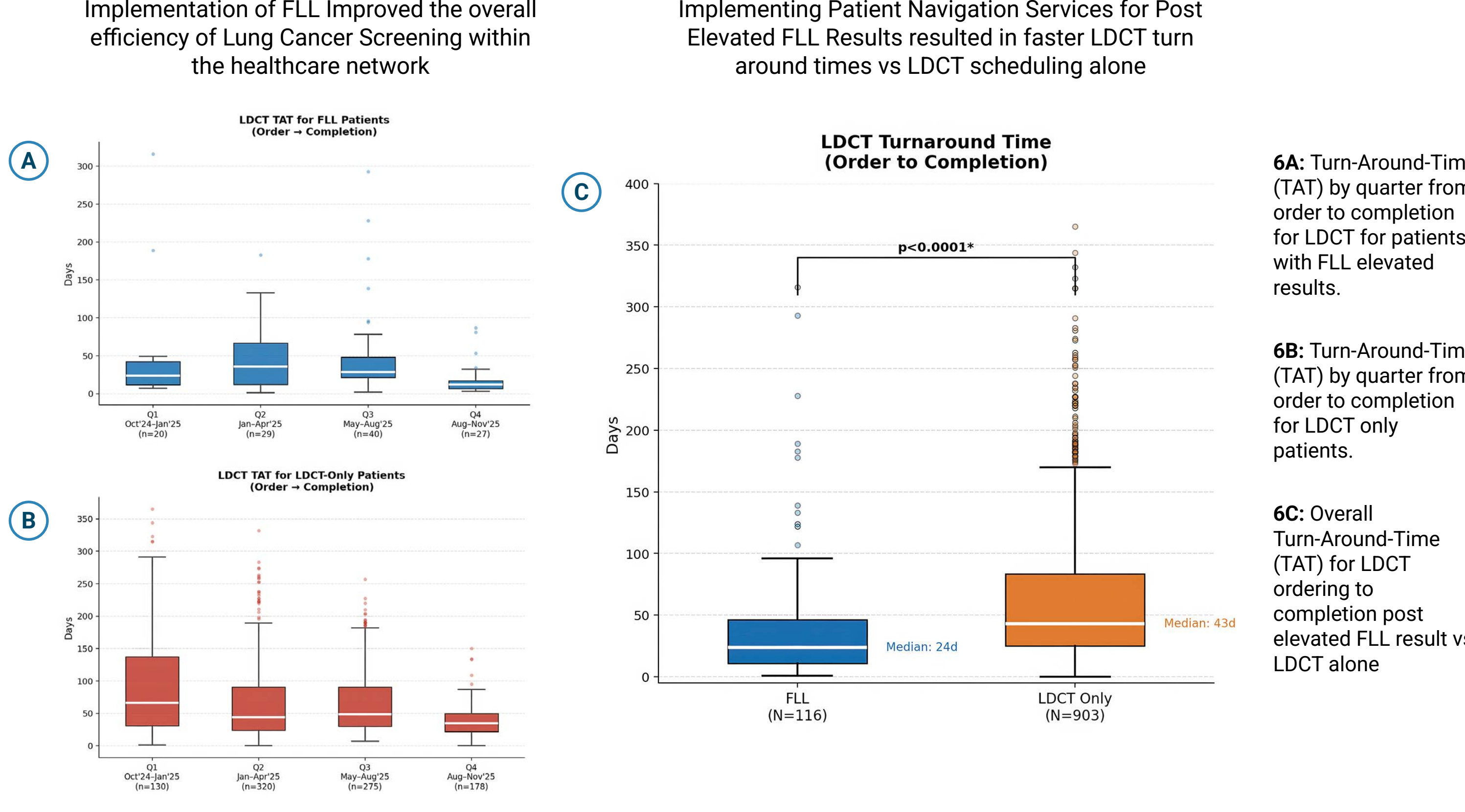
Figure 4: Breakdown of Screening Modalities as Percentage of Total Screened



More than 1 in 4 patients screened chose FLL

Clinic collections are superior to lab collections. Challenges for patients scheduling blood draws and collections from lab settings were overcome by quarter, enabling efficient blood draws with both modalities.

Figure 6: Impact of FLL Implementation on Lung Cancer Screening Program Efficiencies



Implementation of FLL Improved the overall efficiency of Lung Cancer Screening within the healthcare network

Implementing Patient Navigation Services for Post Elevated FLL Results resulted in faster LDCT turn around times vs LDCT scheduling alone

6A: Turn-Around-Time (TAT) by quarter from order to completion for LDCT for patients with FLL elevated results.

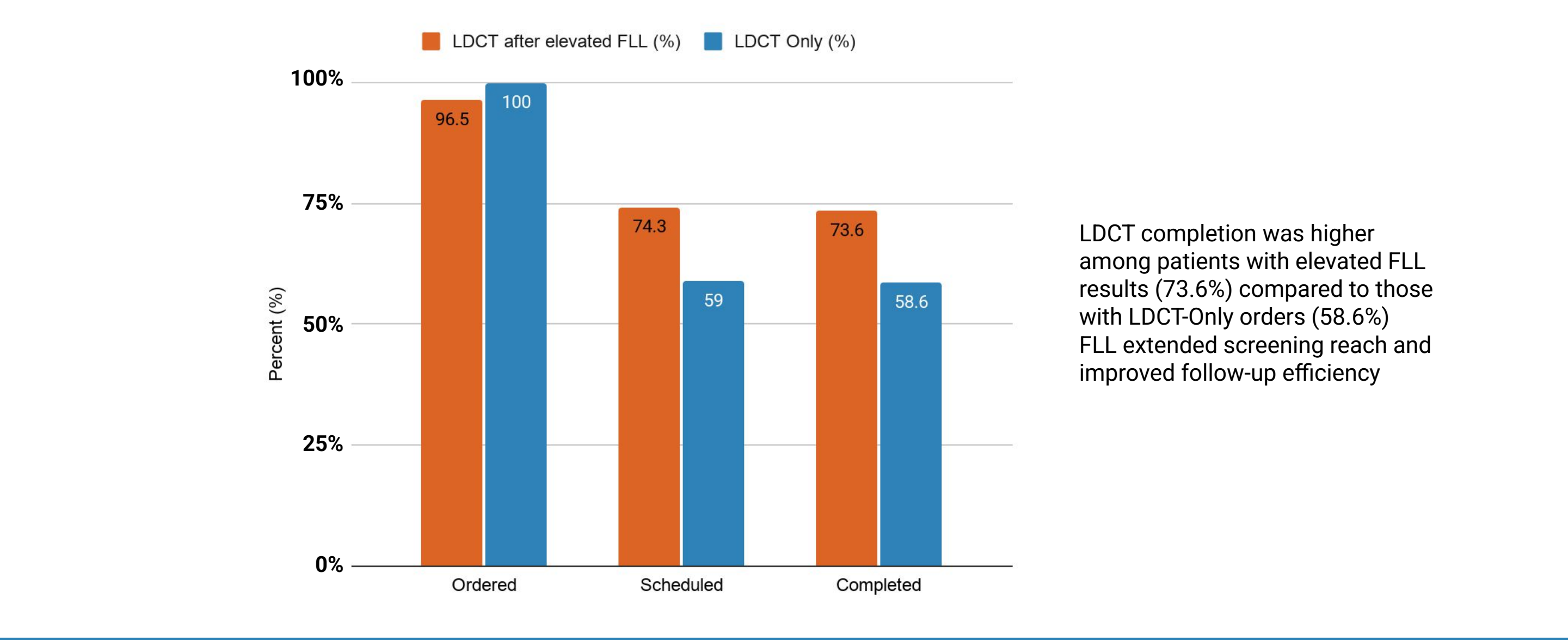
6B: Turn-Around-Time (TAT) by quarter from order to completion for LDCT only patients.

6C: Overall Turn-Around-Time (TAT) for LDCT ordering to completion post elevated FLL result vs LDCT alone

6D: Overall Turn-Around-Time (TAT) for LDCT ordering to completion post elevated FLL result vs LDCT alone

Figure 7: LDCT Order-to-Completion Rates: Post-Elevated FLL vs. LDCT Only

Elevated FLL n=144; LDCT only ordered = 1540



LDCT completion was higher among patients with elevated FLL results (73.6%) compared to those with LDCT-Only orders (58.6%)

Figure 8: Care Coordination Proved Effective With 139 (96.5%) Patients Receiving LDCT Orders and 106 (73.6%) Completing LDCT Post-Elevated FLL Result

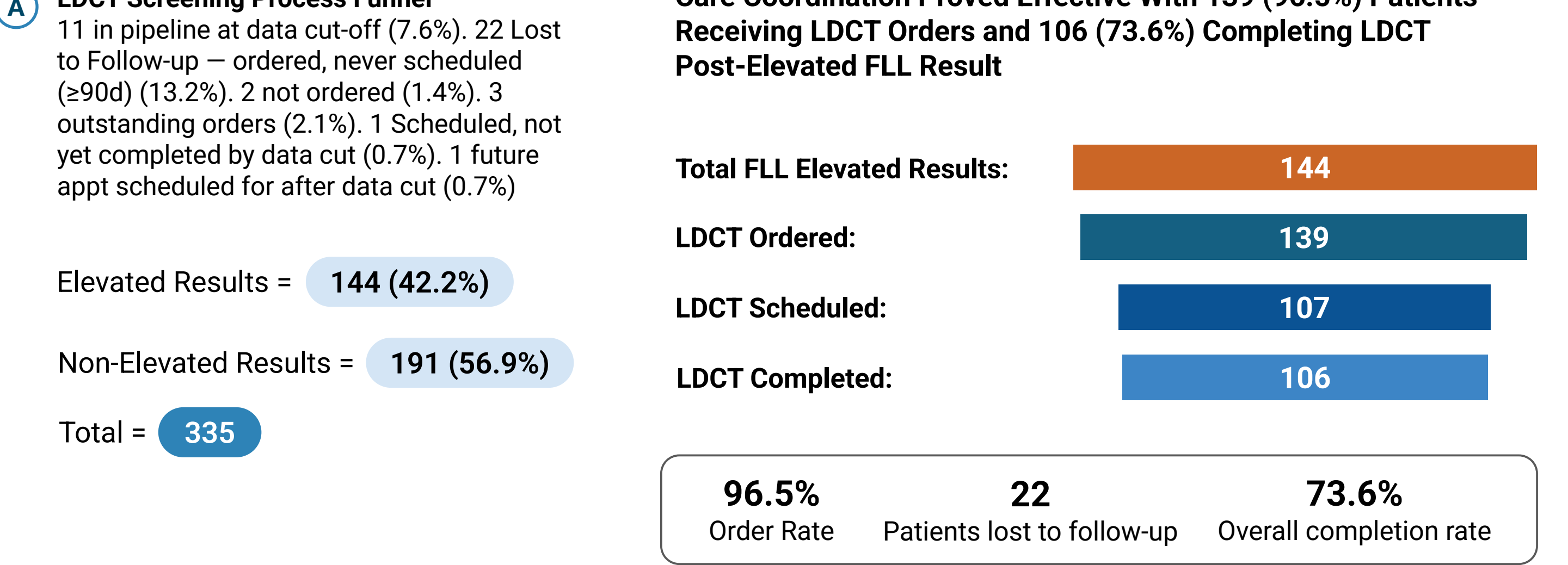


Figure 9: LDCT Results: Of 106 LDCT Results, ~18% (n=19) Resulted in Actionable Findings

LDCT Result	Number of Patients	% Of Total LDCT Results
Lung RADS-0	2	2.8%
Lung RADS-1	31	29.3%
Lung RADS-2	54	50.9%
Lung RADS-3	8	7.6%
Lung RADS-4	1	0.9%
Lung RADS-4A	8	7.6%
Lung RADS-4B	2	1.9%
TOTAL LDCT:	106	

CONCLUSIONS

- Blood-based screening effectively complements the traditional LDCT program when properly integrated into existing care pathways.
- More than 1 in 4 patients chose blood-based screening
- Success factors included EHR integration; payor partnerships; patient navigation, and optimized laboratory collection.
- Reaching 63.7% previously unscreened patients (total 90% behind on screening) with a blood-based screening approach represents meaningful progress toward population-level screening objectives.
 - Additionally, the 96.5% LDCT referral rate and 76.2% LDCT completion rate post FLL-positive results represent meaningful impact on lung cancer screening care gaps.
- Implementation of FLL screening program created process improvements across the whole LDCT LCS continuum of care.
- Navigation efforts continue to close the gap on patient follow-through.

These findings provide actionable insights for expanding lung cancer screening access through First-Look Lung blood-based methodology across diverse healthcare delivery models