

## BACKGROUND

Lung cancer early detection with Low-Dose Computed Tomography (LDCT) has proven efficacy in reducing mortality,<sup>1,2</sup> however, persistently low screening rates compounded by geographic access barriers, socioeconomic disparities and patient compliance has limited population-level benefit.<sup>3</sup>

The FIRSTLUNG L301 (NCT06145750)<sup>4</sup> Clinical Utility Study is a prospective, cluster randomized controlled trial to assess the impact of a blood-based screening test (pWGFRag-Lung, FirstLook Lung)<sup>5</sup> on lung cancer screening utilization.

Patients adhering to annual lung cancer screening were excluded; only USPSTF eligible patients that were behind on screening were included.

Baseline analysis of socioeconomic data is an important component to understand the real world impact of the approach on a national scale

A central intent of this initiative was to assess the impact of blood-based screening across a wide socioeconomic range.

## METHODS

Clinic catchment area socioeconomic deprivation was explored post-hoc using the Area Deprivation Index (ADI; The Neighborhood Atlas),<sup>6</sup> which assigns census block group-level scores (1=least to 100=most disadvantaged) to ZIP code catchment areas by assessing 4 key themes: Income, education, employment, housing quality.

A complementary post-hoc exploratory analysis was performed using the CDC/ATSDR Social Vulnerability Index (SVI)<sup>7</sup>, which assesses vulnerability across four domains that are also relevant to lung screening access: socioeconomic status; household characteristics; racial and ethnic minority status; housing type and transportation.

A patient-weighted mean ADI (and SVI) was derived for each clinic catchment area as a proxy for the socioeconomic profile of the patient population participating.

Clinics were categorized into tertiles based on the ADI of their individual catchment areas: least disadvantaged (ADI 1–33), middle (34–66), and most disadvantaged (67–100); and into quartiles based on the SVI of their catchment areas: least vulnerable (SVI <0.25), low-moderate (0.25–0.49), moderate-high (0.50–0.74), and most vulnerable (≥0.75)

## RESULTS

- Twenty-seven clinics with ADI data were explored post-hoc (98.8% patient coverage, n = 7,009 / 7,097)
  - One clinic, out of 28, was excluded from this analysis due to incomplete ADI data (88 patients, 1.2%).
- All 28 clinics with SVI data were explored post-hoc (100% patient coverage, n = 7,097)
- Census block groups within clinic catchment areas ranged from ADI 4 to 97
- Clinic-level mean ADI ranged from 17.6 to 83.7.
- Patient-weighted mean ADI: 43.1 (SD 17.7) across 27 practices
- North Carolina practices mean DPI: 40.1 (SD 15.3, 20 practices, 5,953 patients)
- Florida practices mean DPI: 60.3 (SD 22.9, 7 practices, 1,056 patients)

REFERENCES:  
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 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: "Addressing disparities in lung cancer screening eligibility and healthcare access: an official American Thoracic Society Statement". Rivera MP, Katki HA, Tanner NT, et al. Am J Respir Crit Care Med. 2020;202(7):e95-e112.  
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 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.  
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 https://www.atdsr.cdc.gov/place/health/svi/data\_documentation\_download.html Accessed on April 29, 2026.

\*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.

Figure 1: The FIRSTLUNG Study Design

Can a blood-based lung cancer screening test increase lung cancer screening rates in primary care?

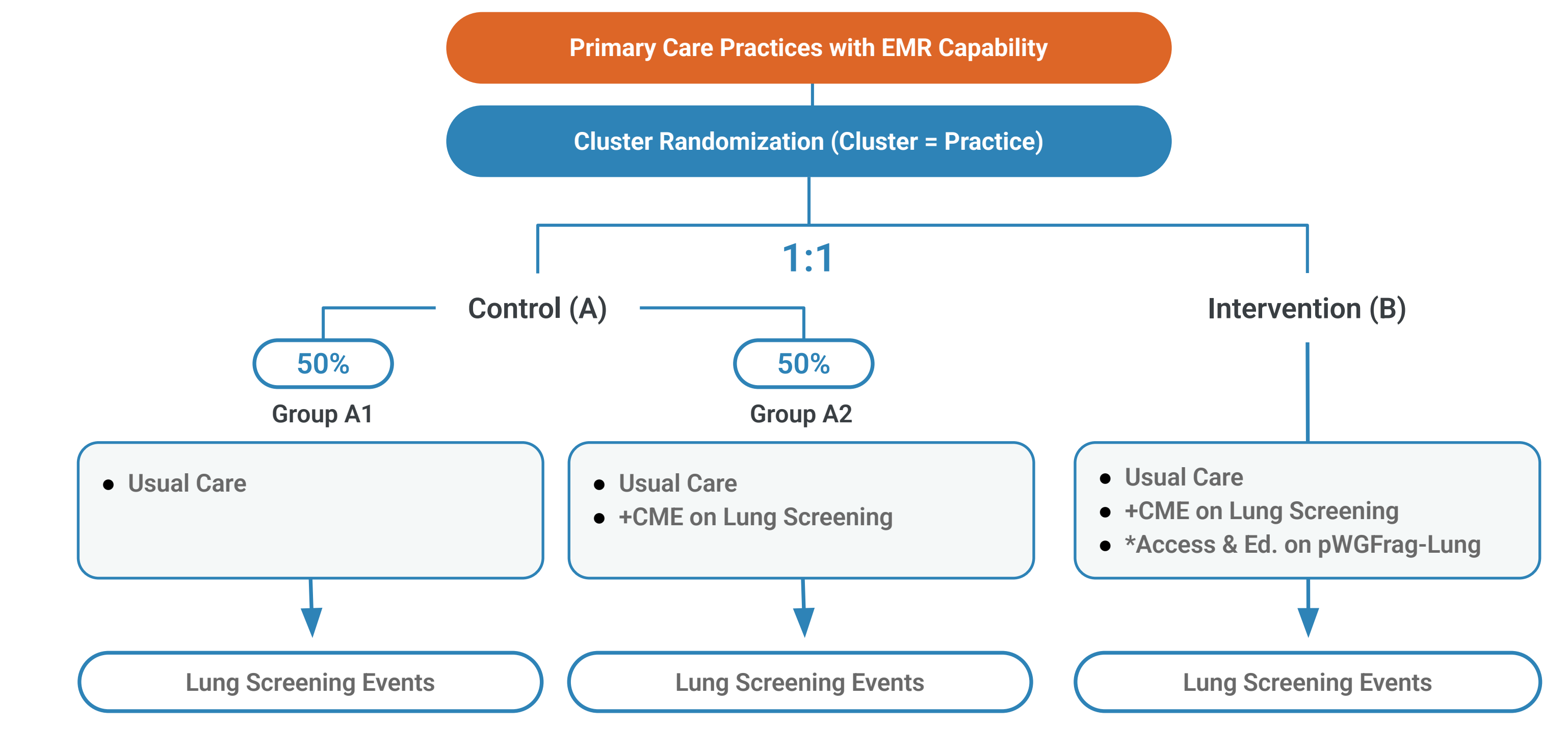


Figure 2: Blood-based Testing Clinical Workflow pWGFRag-Lung (FirstLook Lung)

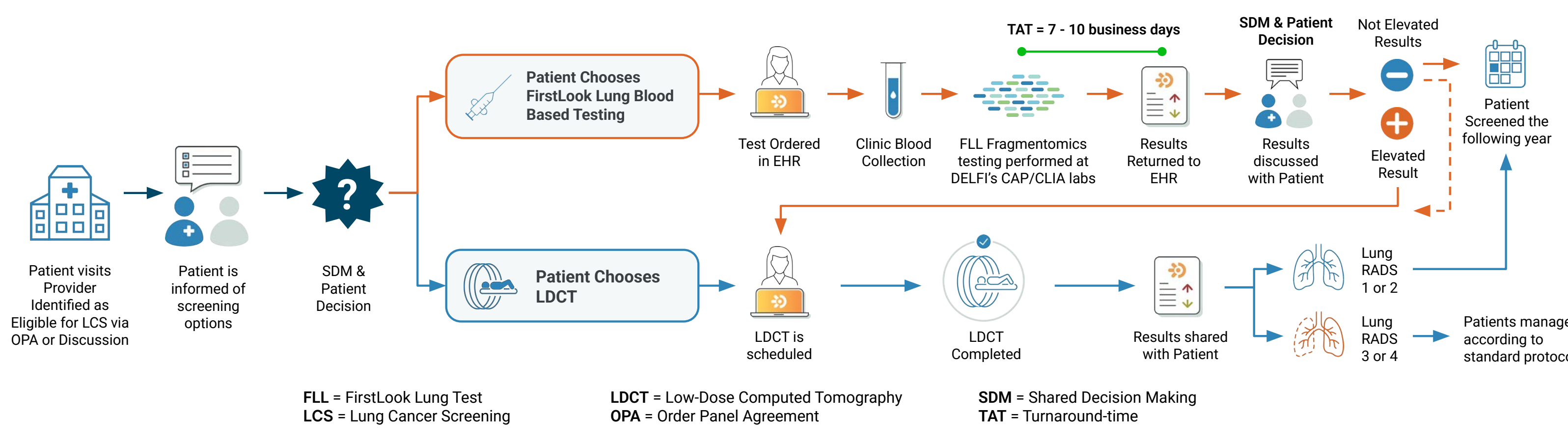


Table 1: 28 Clinics were Cluster Randomized. Overview of Clinic Catchment Area by ADI.

	Count	Percent (%)
Clinics with ADI data	27 / 28	96.4
Total patients enrolled in clinics with ADI data	7,009 / 7,097	98.8
Clinic Level Mean ADI	17.6 to 83.7	-
Patient-weighted mean ADI	43.1	-
Tertile 1 (ADI 1–33)	11 clinics	40.7
Tertile 2 (ADI 34–66)	13 clinics	48.1
Tertile 3 (ADI 67–100)	3 clinics	11.1

Table 2: Overall Balance of Area Deprivation Index of Clinic Catchment Area Between Study Arms (weighted by number of patients enrolled per clinic)

	Arm A (Control)	Arm B (Intervention)
Sites (w/ ADI)	15 (14 <sup>a</sup> )	13
Number of Patients	3941 (3853 <sup>a</sup> )	3156
ADI Range, Site Level	17.6 - 71.3	19.0 - 83.7
Patient-weighted mean ADI	41.4	45.2
T1 sites (ADI 1–33)	6 clinics 1,314 pts (34%)	5 clinics 456 pts (14%)
T2 sites (ADI 34–66)	7 clinics 1,926 pts (50%)	6 clinics 2,269 pts (72%)
T3 sites (ADI 67–100)	1 clinic 613 pts (16%)	2 clinics 431 pts (14%)

<sup>a</sup> = One clinic with 88 patients allocated was excluded from these analyses due to no ADI data reported within The Neighborhood Atlas.

ADI = Area Deprivation Index

Pts = Patients

T = ADI Tertile (where 1 is the lowest and 100 is the highest possible index of deprivation)

Figure 3: Enrolled Clinics Span the Full Range of Area Deprivation Indexes with Comparable Distribution Across Arm

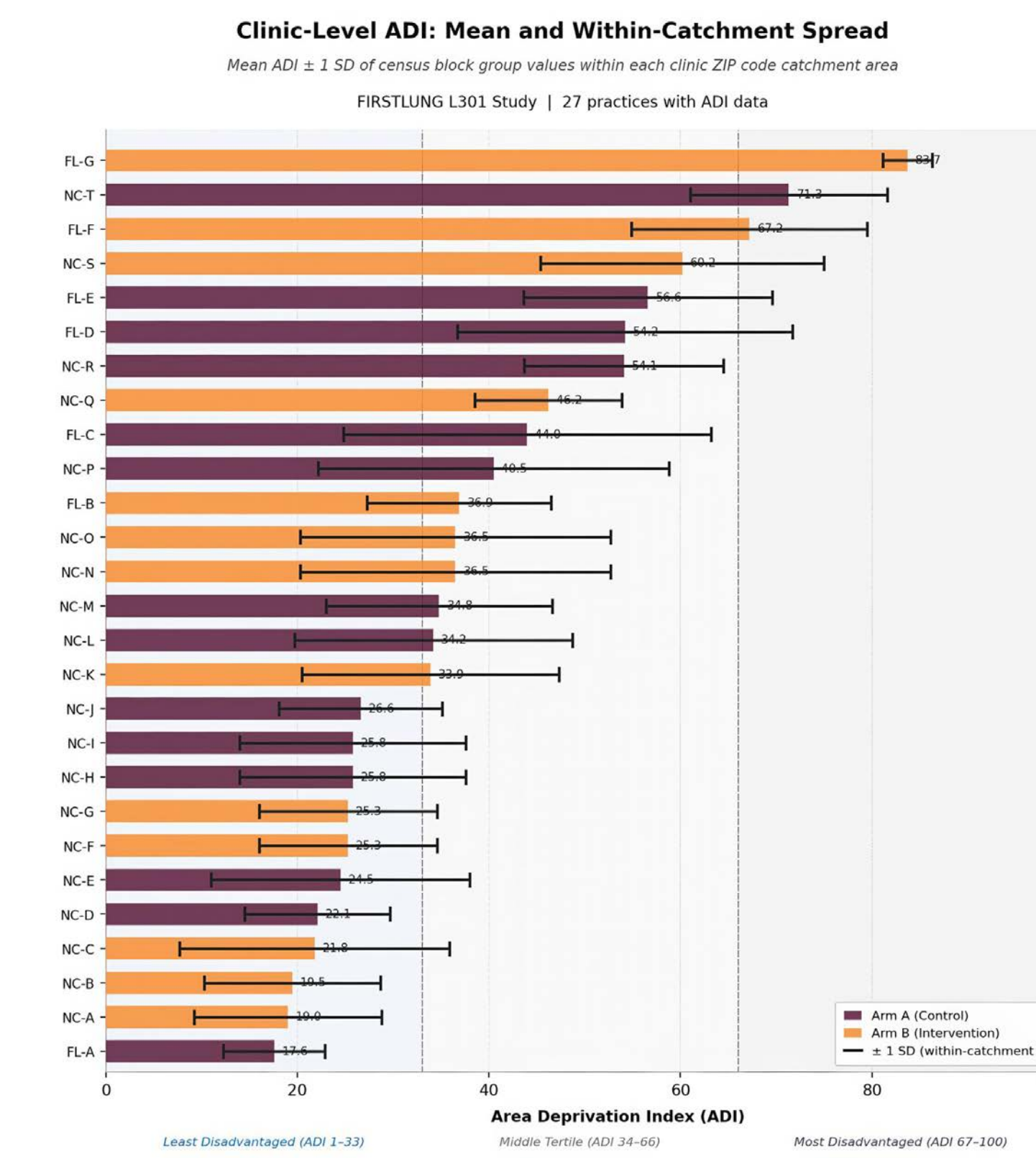


Figure 4: Clinics Enrolled in FIRSTLUNG Reflect a Wide Range of Area-Level Socioeconomic Disadvantage (Patient Enrollment-weighted clinic catchment area mean ADI)

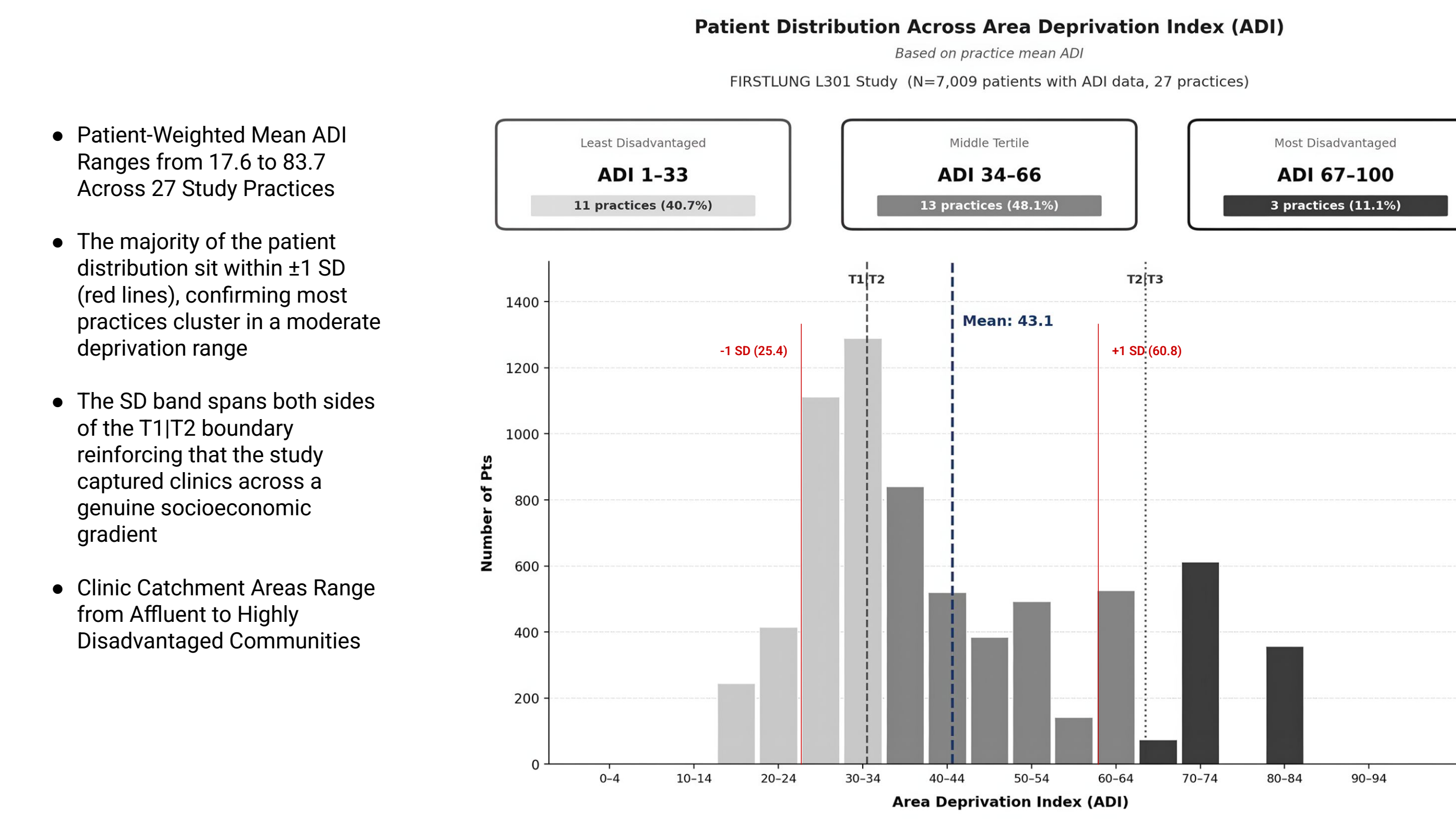


Figure 5: Cluster Randomization Achieved Comparable Socioeconomic Distribution Across Arms

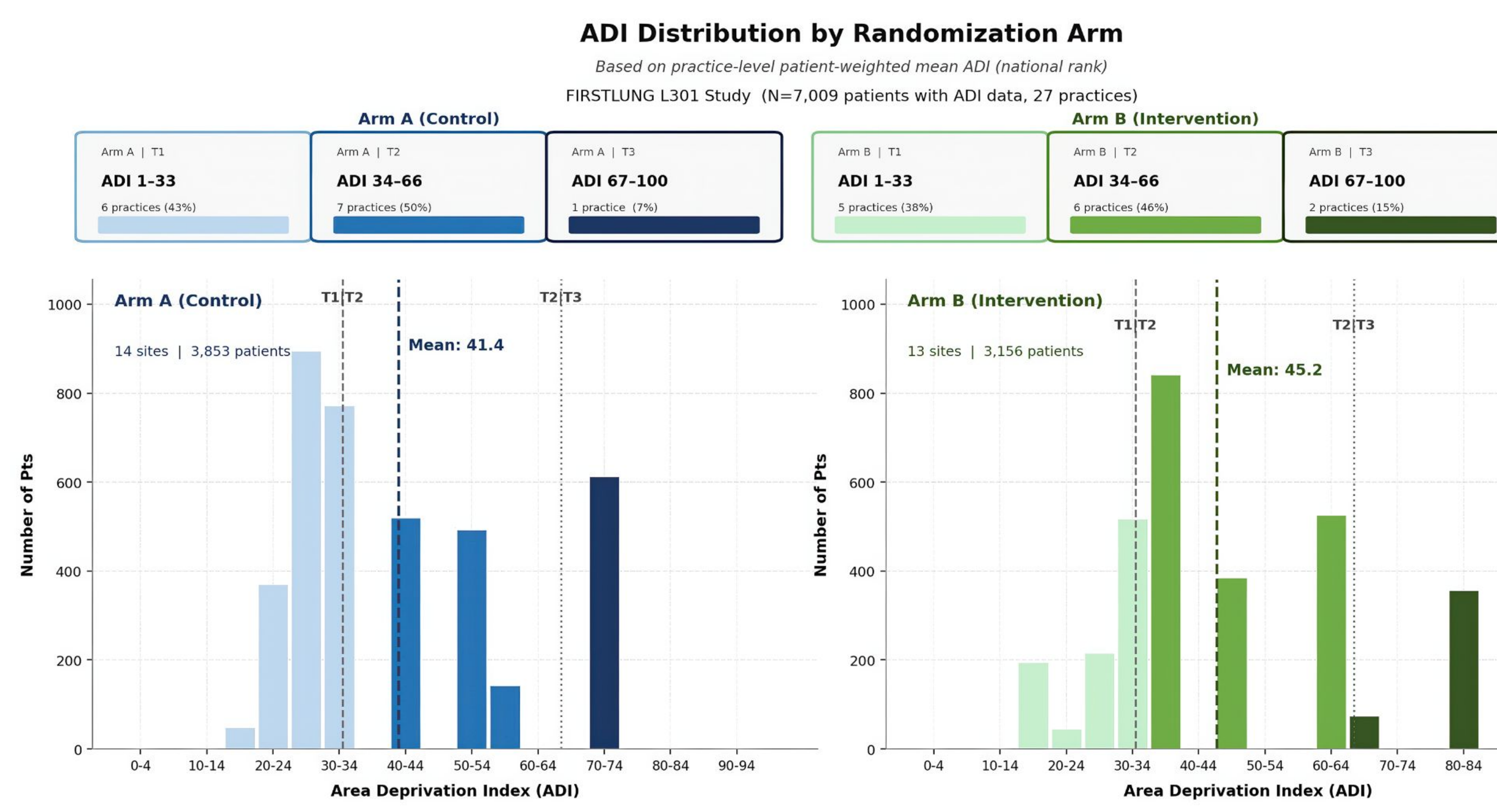
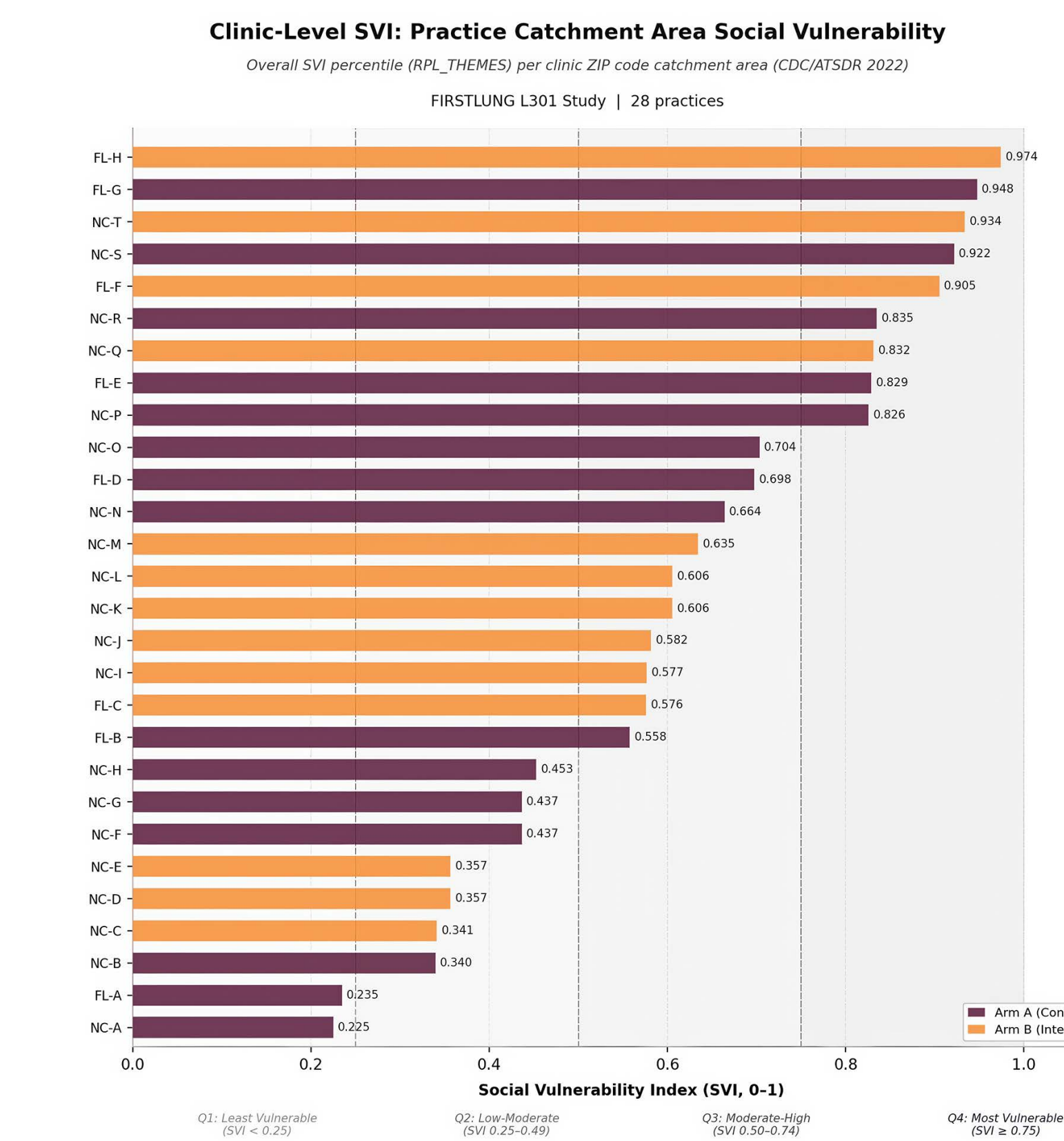
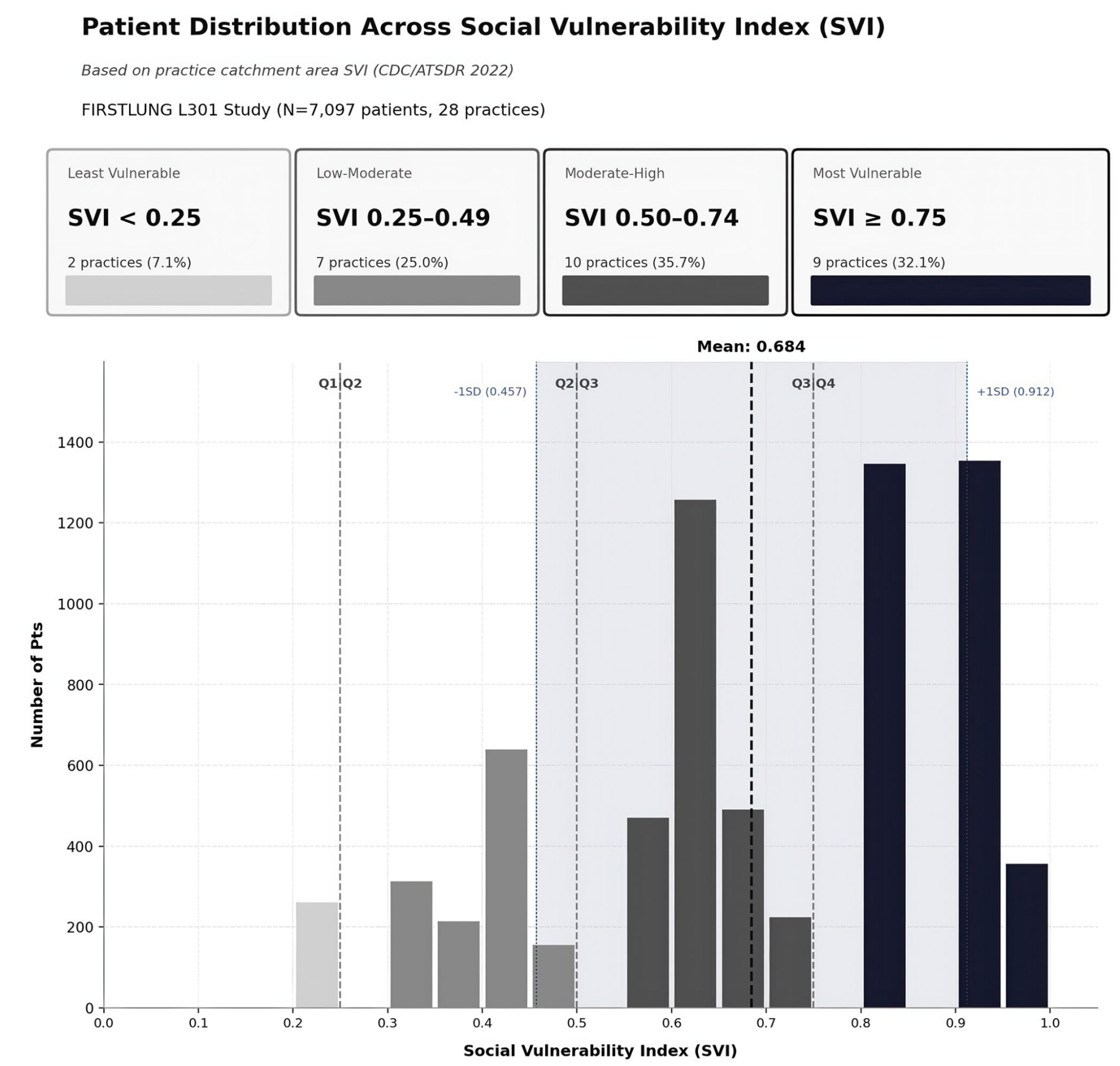


Figure 6: Enrolled Clinics Span the Full Range of Social Vulnerability with Comparable Distribution Across Arm



Clinic-level SVI (mean 0.684 ± 0.211) across 28 Clinics with available SVI data, independently confirms enrollment across a wide range of socially vulnerable communities, with the majority of clinics in moderate-to-high vulnerability communities

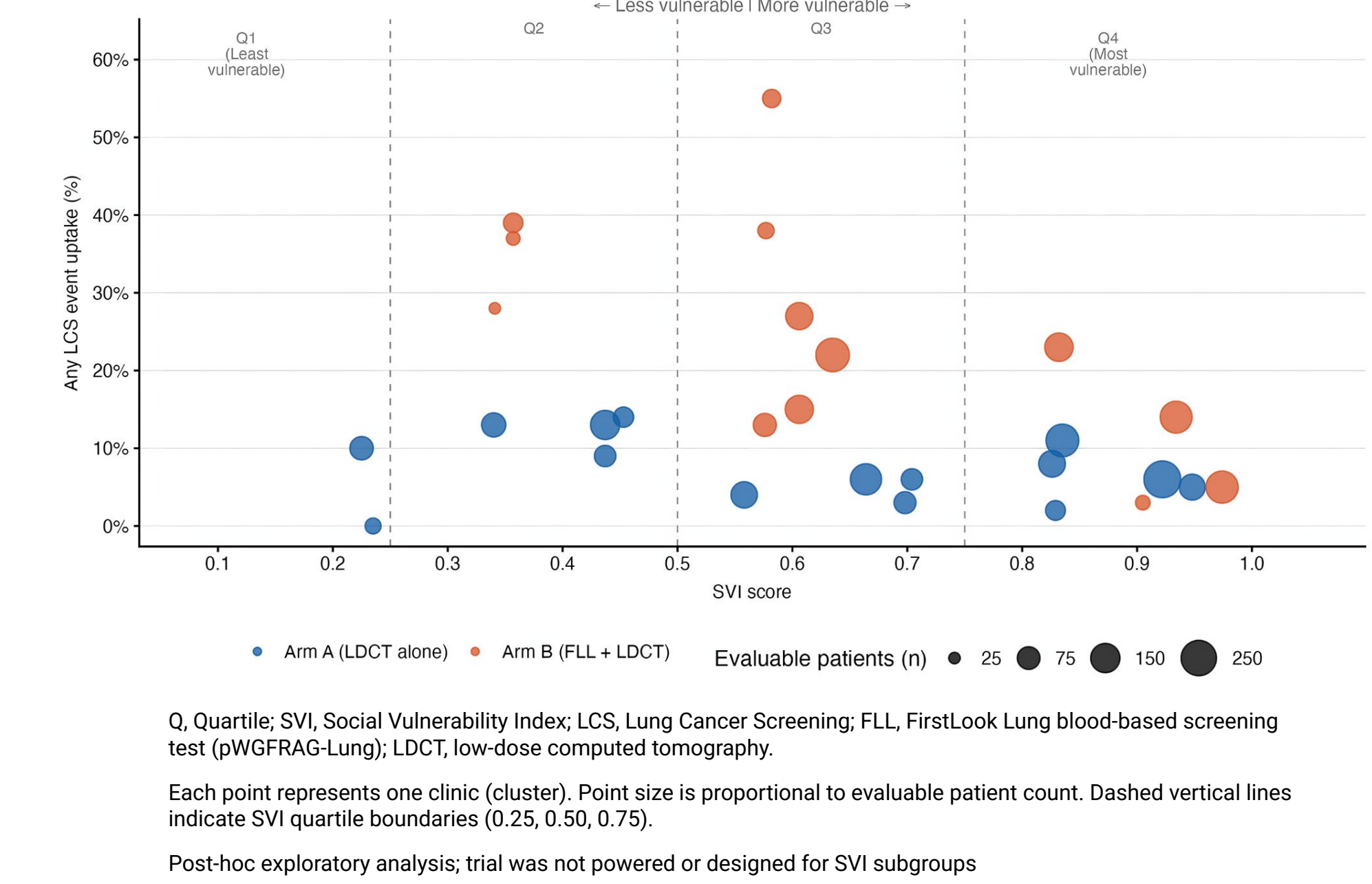
Figure 7: Social Vulnerability Index Confirms Enrollment Across the Full Spectrum of Community Vulnerability (Patient Enrollment-weighted clinic catchment area mean SVI)



- Patient-weighted mean SVI of 0.684. (n = 28 sites with available SVI data)
- Enrolled clinics span the full range of national social vulnerability (SVI 0.225–0.974)
- 68% of practices serve communities in the upper half of vulnerability (SVI ≥ 0.50) and a SVI captures dimensions of vulnerability beyond economic deprivation – including disability, limited English proficiency, racial and ethnic minority status, and housing and transportation barriers – that are directly relevant to lung cancer screening access. Further analysis illustrates study arms are also reasonably well-matched by SVI, with a modest difference of +0.059 favoring Arm B being slightly more vulnerable consistent with the ADI analysis.

Figure 8: Post-hoc Exploratory Analysis of Lung Cancer Screening Uptake by Study Arm Across Social Vulnerability Index Quartiles

Arm B (screening event = either blood-based test or LDCT) appears to outperform Arm A (LDCT only) in Q2, Q3, and Q4 (i.e., across the low-moderate vulnerability to high-vulnerability spectrum) in this exploratory analysis.<sup>‡</sup>



## CONCLUSIONS

- The FIRSTLUNG L301 study successfully enrolled clinics spanning a diverse socioeconomic spectrum, from affluent (ADI 17.6) to highly disadvantaged communities (ADI 83.7).
  - 98.8% ADI coverage across 27/28 clinics with representation across all socioeconomic tertiles
- SVI analysis of all 28 clinics enrolled confirms and extends the ADI findings across a second, complementary socioeconomic framework.
- Arm B Intervention (with access to the blood-based test), out-performed Arm A (usual care) in areas of low-to-moderate to high Social Vulnerability<sup>‡</sup>

1. This study successfully enrolled clinics spanning a broad socioeconomic spectrum, providing appropriate context to evaluate the impact of blood-based screening on lung cancer screening rates in populations affected by access barriers.
2. In post-hoc exploratory analysis, blood-based screening positively impacts uptake across the social vulnerability spectrum, including in communities where barriers are greatest.<sup>‡</sup>

LIMITATIONS OF THE ANALYSIS:  
 1: The ADI relies on American Community Survey (ACS) data. Results are subject to the limitations of ACS data.  
 2: This is a cluster randomized trial with clinicians as the human subject, as such, patient level data for zip code and DPI is not possible to collect and can only be inferred based on practice zip code service area. Some clinics serve patients within a range of DPIs, however only average DPI per clinic are available for the patient-weighted DPI analysis.  
 3: ADI values are measured by census block group, as such, limitations exist in linking ADI units to zip codes that do not map precisely.  
 4: The SVI analysis is subject to the same limitations as ADI. Additionally, the score aggregates the four thematic domains with equal weighting – may mask variation in specific vulnerability dimensions relevant to lung cancer screening access.  
<sup>‡</sup> ADI/SVI distribution and outcome of Lung cancer uptake is post-hoc exploratory analysis; trial was not powered or designed for SVI/ADI subgroup and is also subject to limitations above.