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# Update from CONFIRM: A Trial of 50,000 US Veterans Randomized to Colonoscopy vs. FIT

**Jason A. Dominitz, MD, MHS**

**on behalf of the CSP #577 CONFIRM Investigators**



# Acknowledgements

***CONFIRM is funded and being conducted by  
the Cooperative Studies Program***

***Office of Research and Development***

***Department of Veterans Affairs***

***The contents of this presentation do not represent the views  
of the US. Department of Veterans Affairs or the United  
States Government***

# Background: CONFIRM Study

Randomized controlled trial

Screening colonoscopy vs. annual FIT screening (1:1 randomization)

Average risk adults aged 50-75 & due for CRC screening

- Exclude those with personal history of adenoma/cancer, family hx of CRC, or signs or symptoms warranting colonoscopy

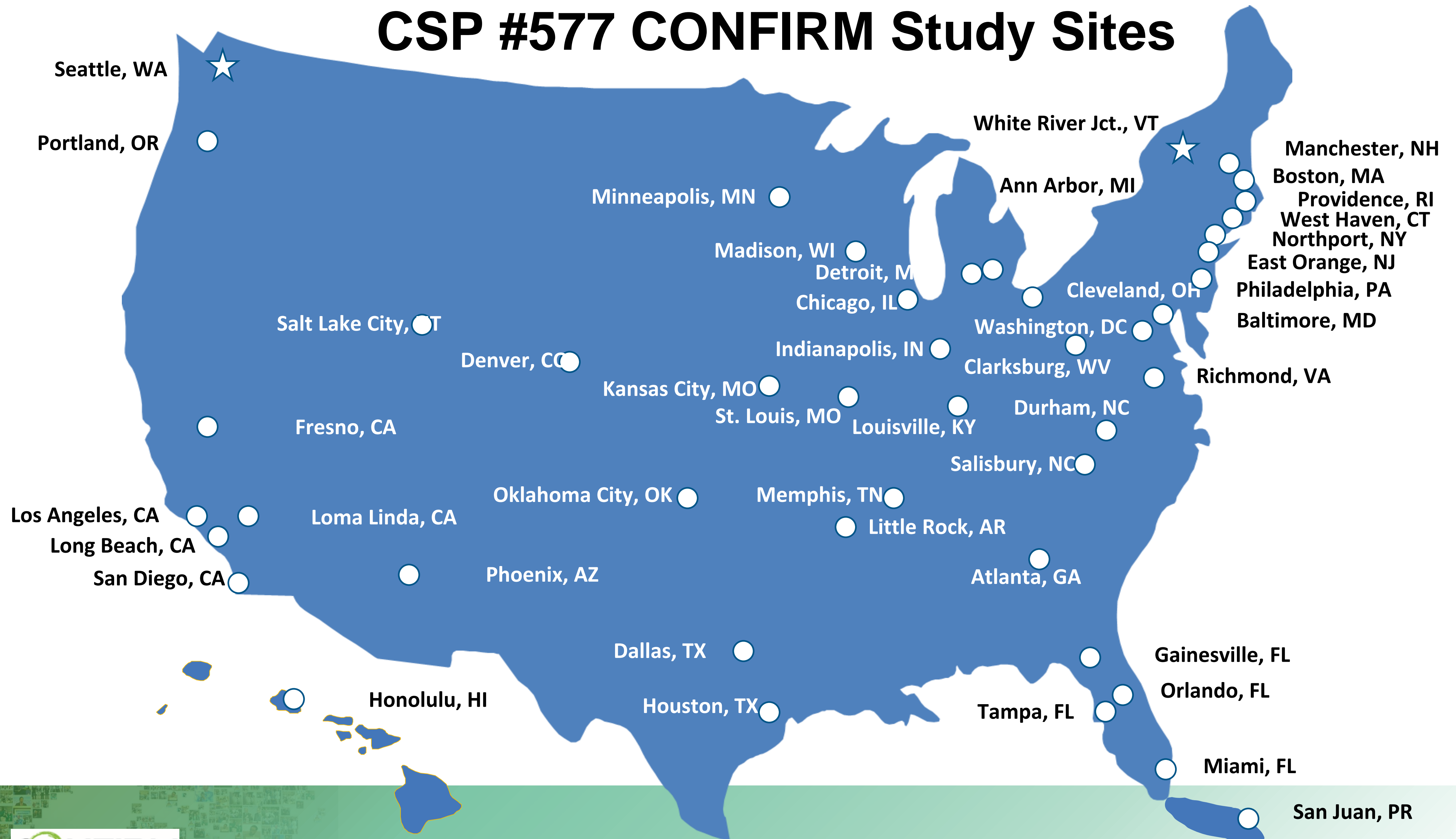
Primary outcome: CRC mortality over 10 years

Recruitment May 12, 2012-December 1, 2017

46 VA Medical Centers



# CSP #577 CONFIRM Study Sites



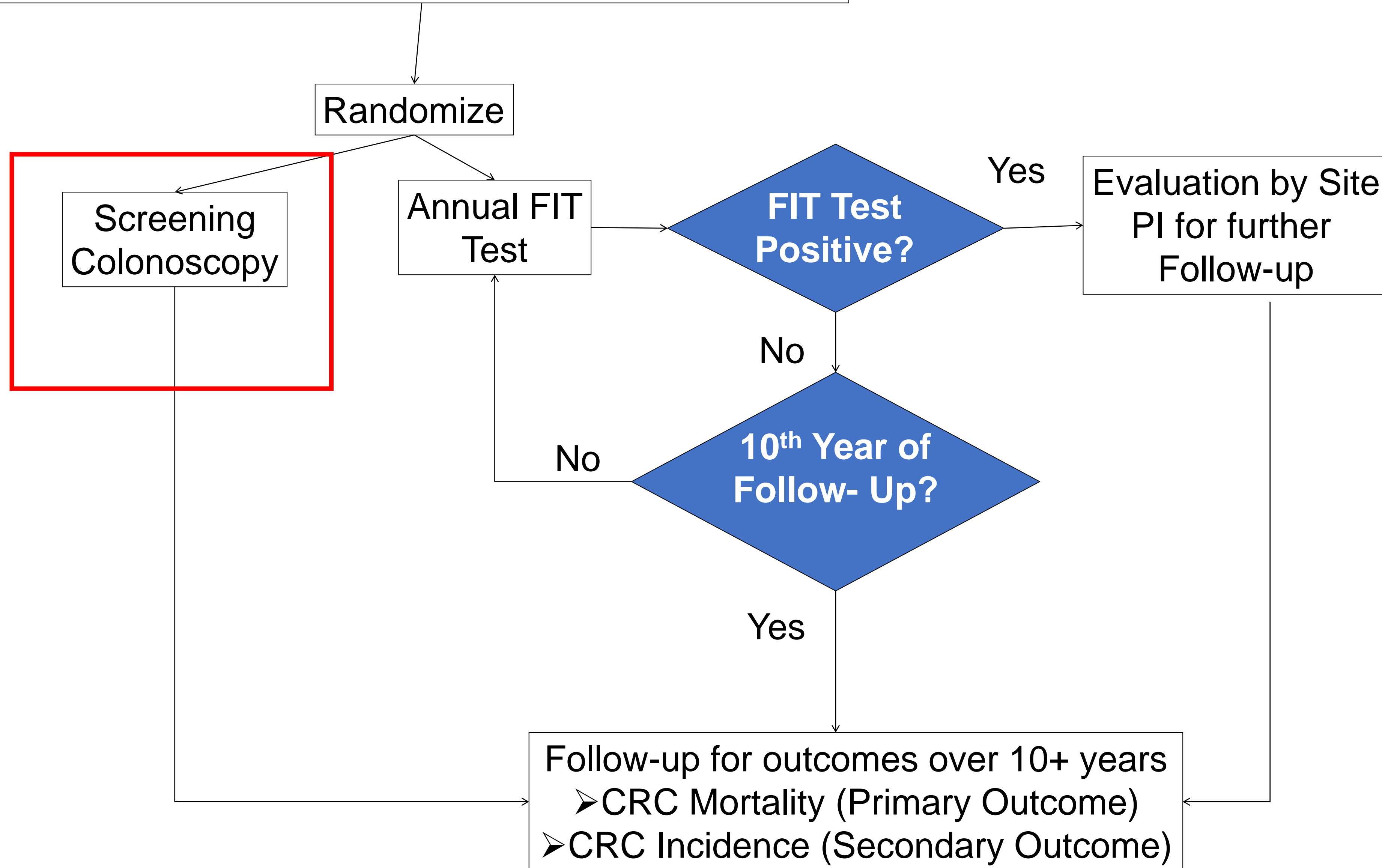
# Background

1. Adherence to FIT is critical to its effectiveness
2. While US guidelines recommend annual FIT, biennial FIT is common in other countries
3. Factors associated with FIT adherence are not well described

# Aims

1. To review screening colonoscopy findings in the CONFIRM Study
2. To describe longitudinal FIT adherence

Recruit 50,000 'screen eligible' Veterans (Age 50-75)



Randomized screen eligible' Veterans (Age 50-75)  
N=50,126

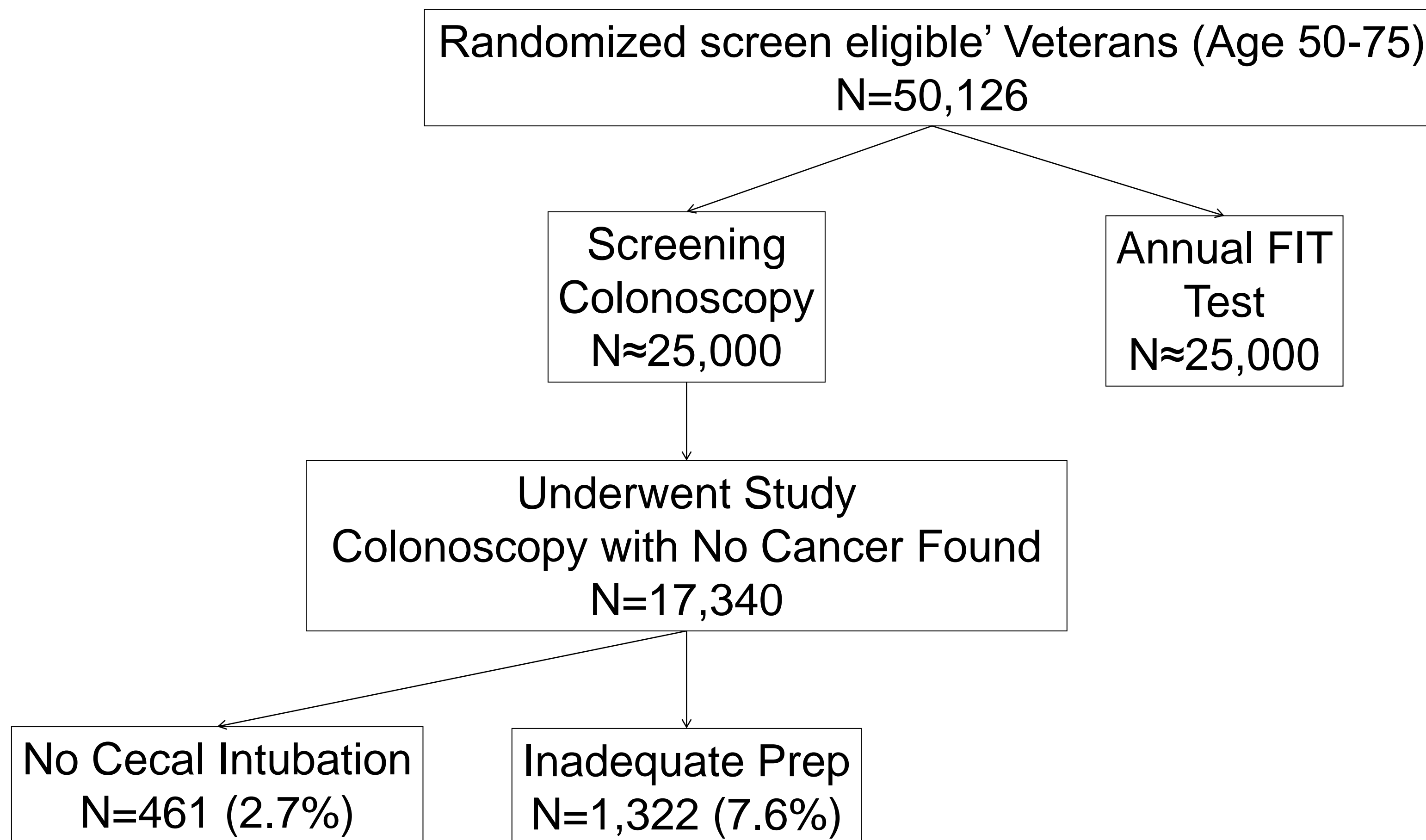
Screening  
Colonoscopy  
N≈25,000

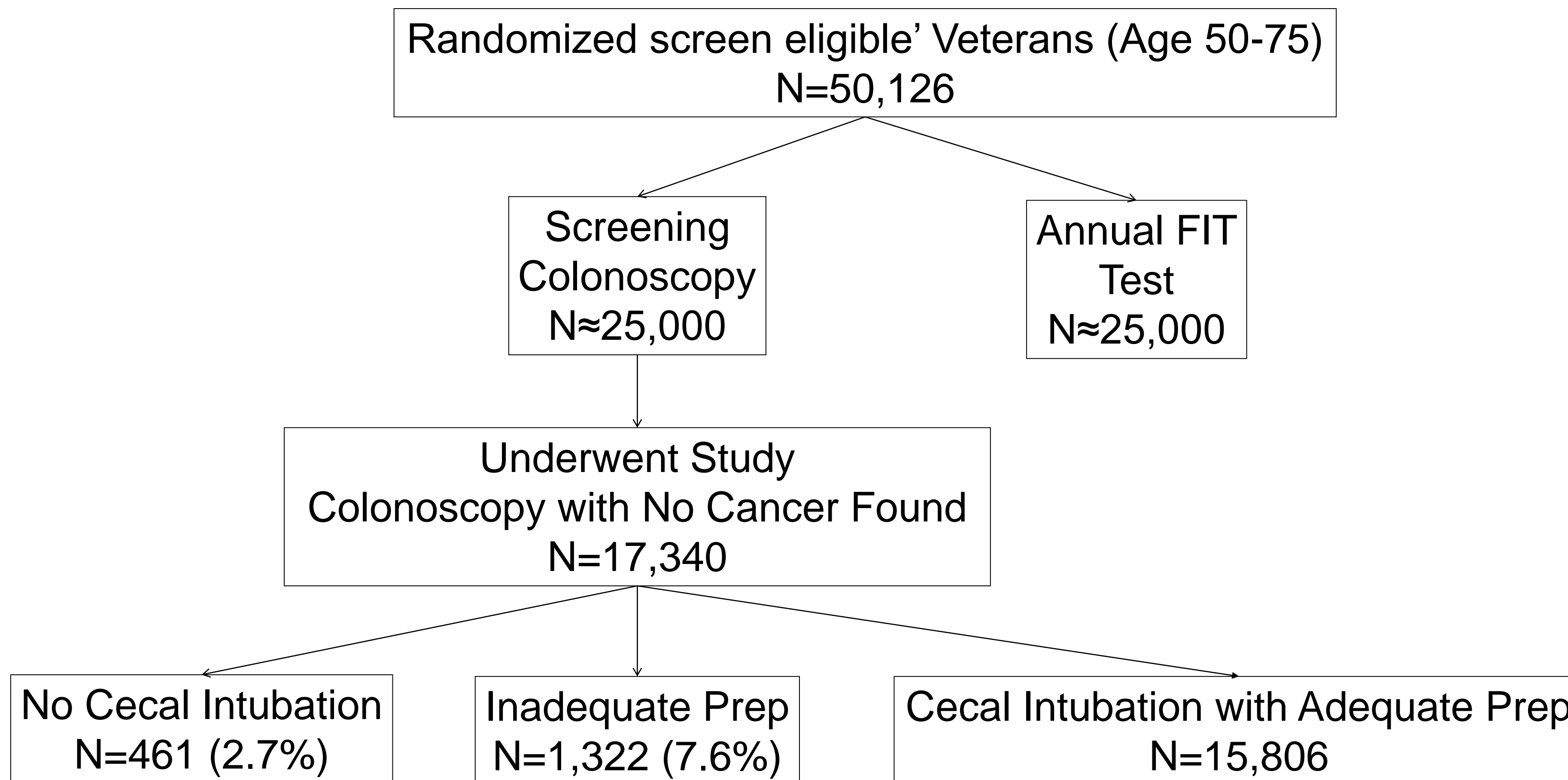
Annual FIT  
Test  
N≈25,000

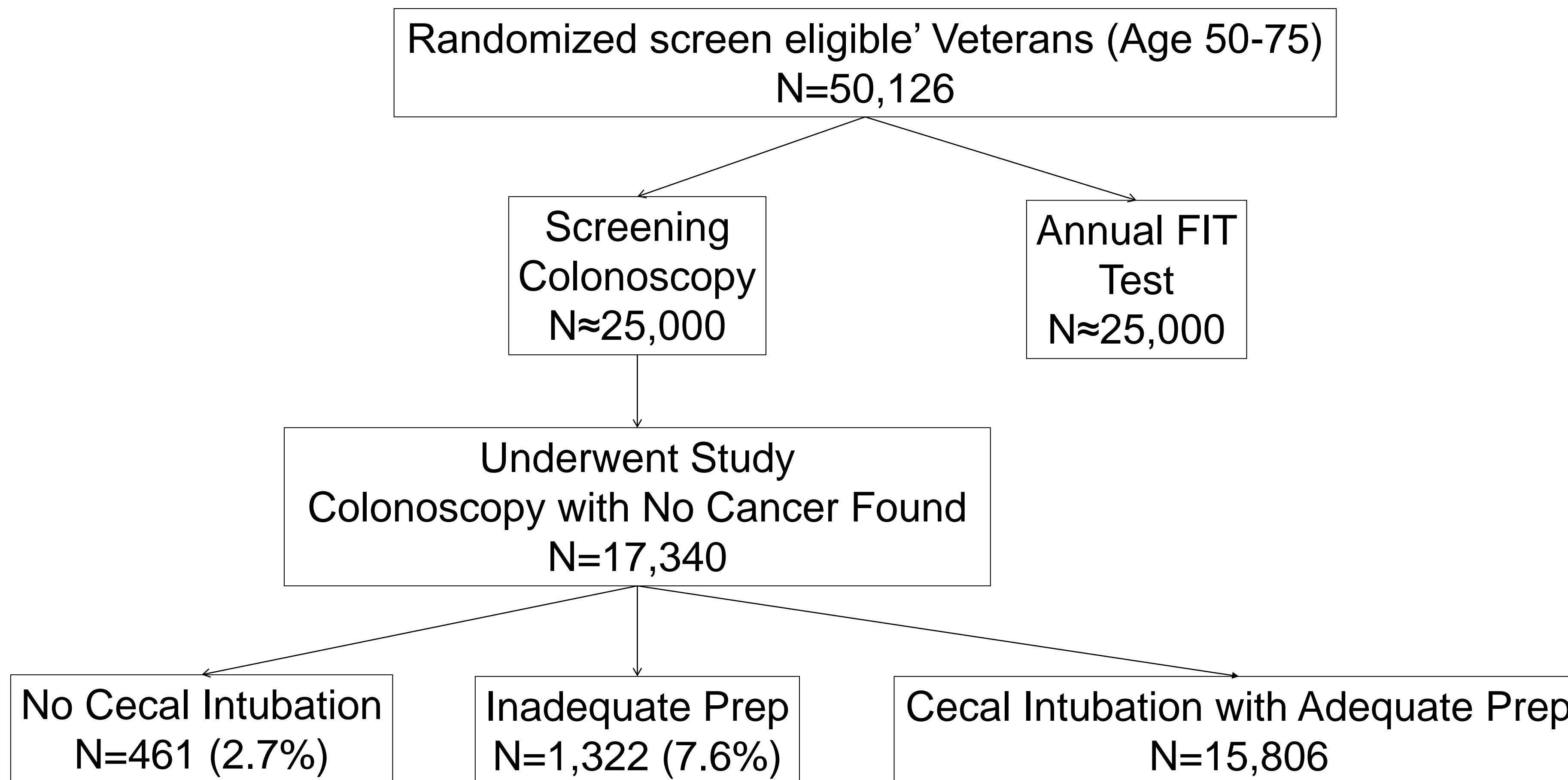
Underwent Study  
Colonoscopy with No Cancer Found  
N=17,340

No Cecal Intubation  
N=461 (2.7%)

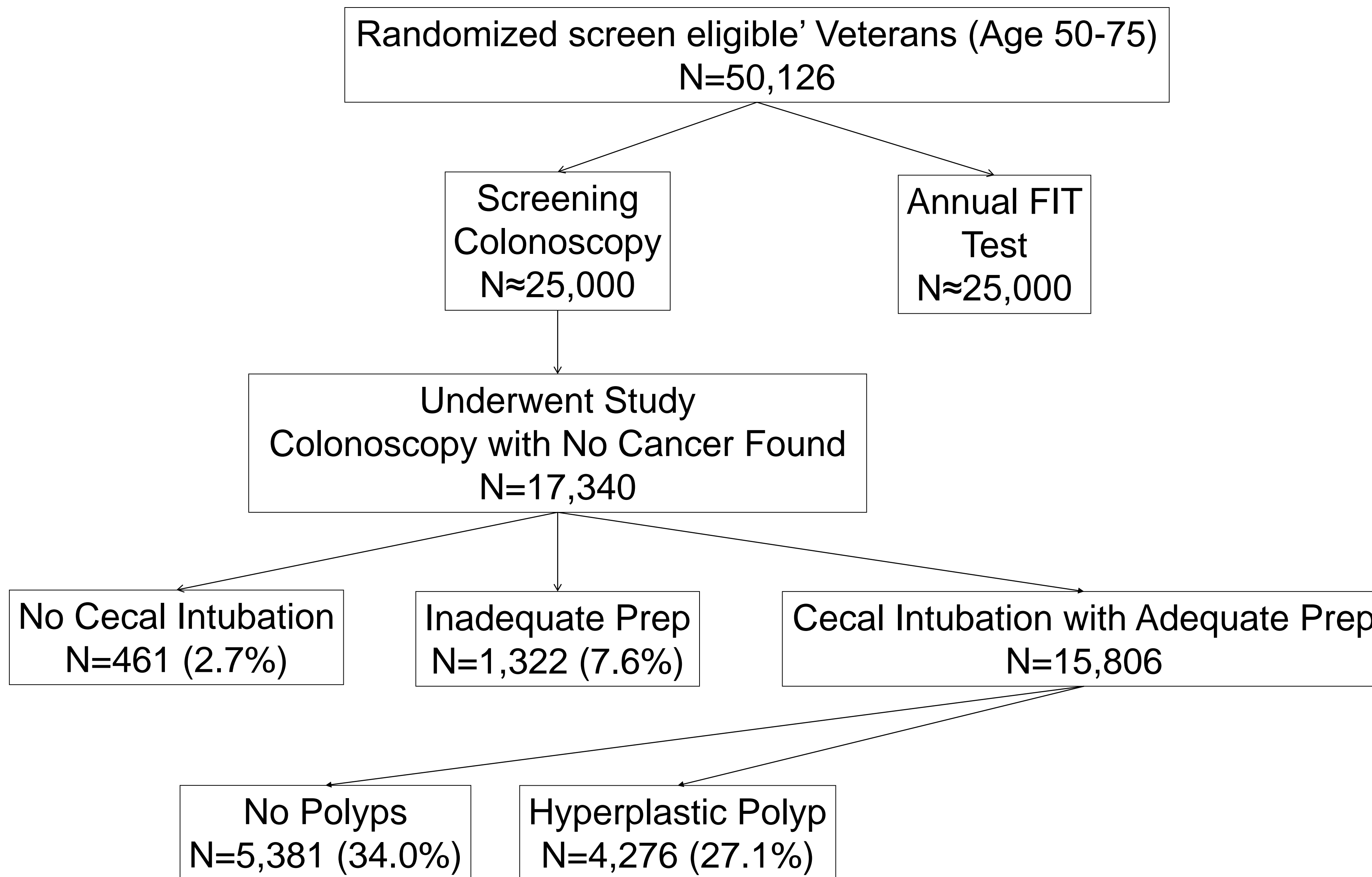


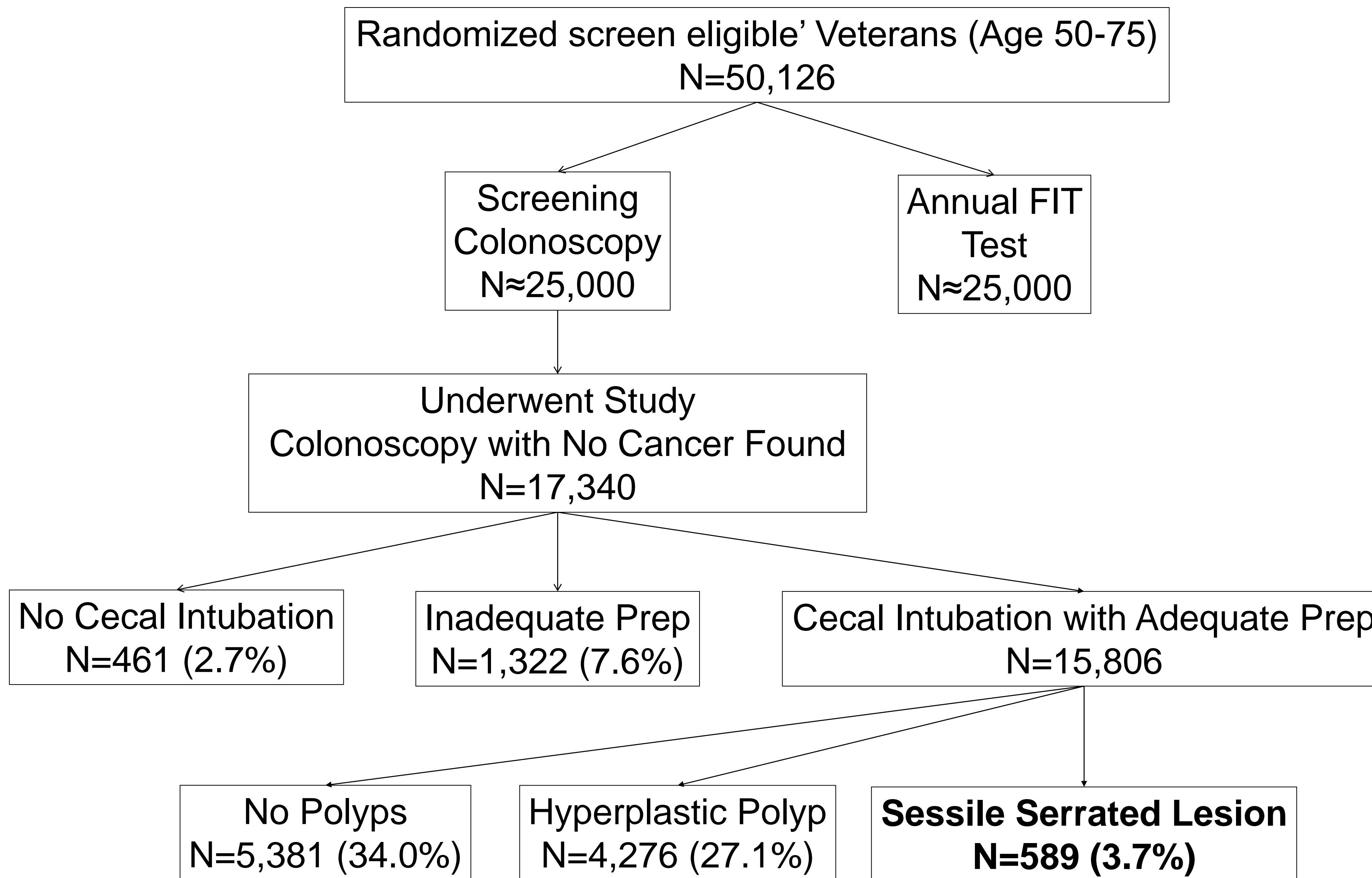




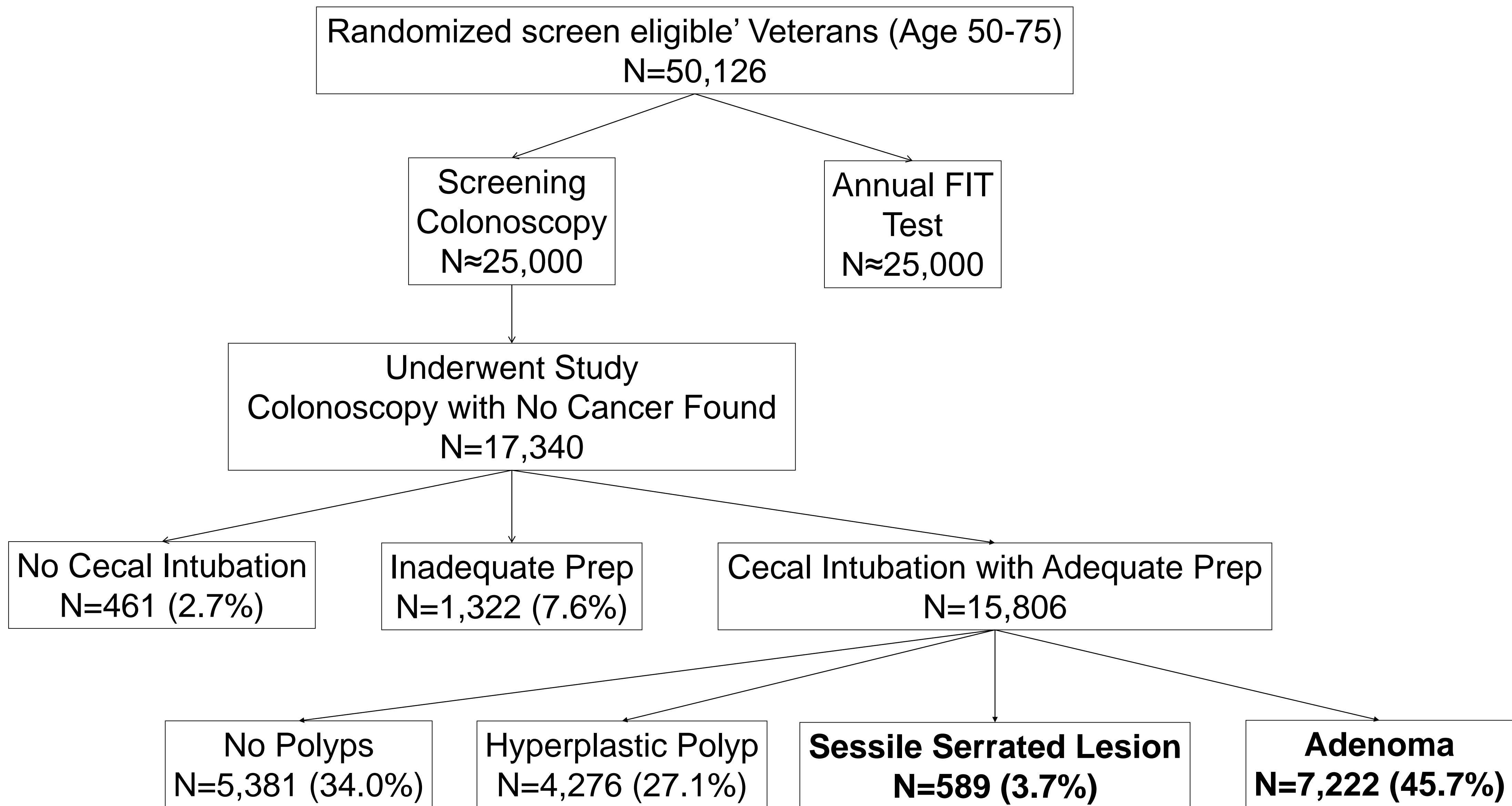


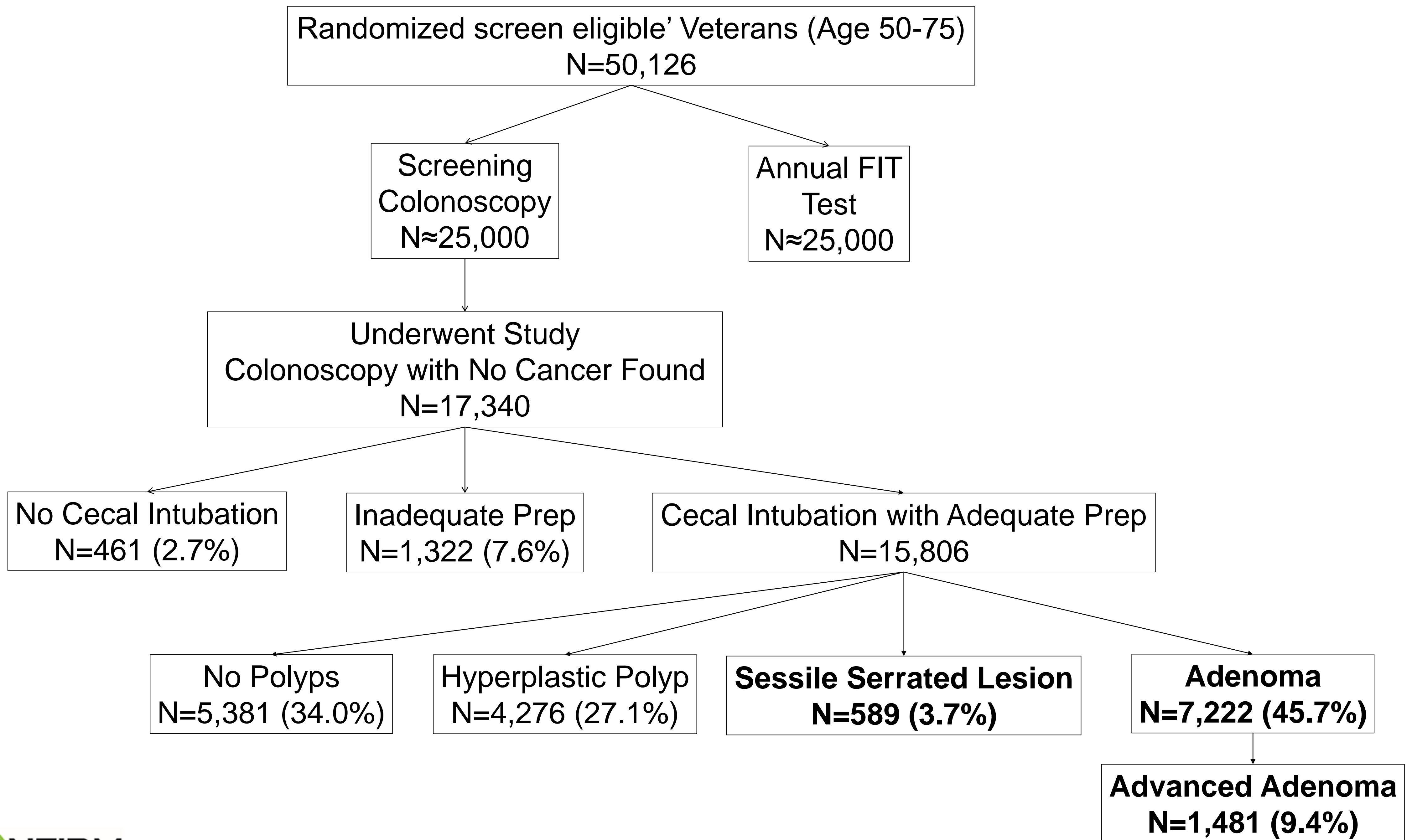
Average withdrawal time (no polyps) = 11.1 minutes



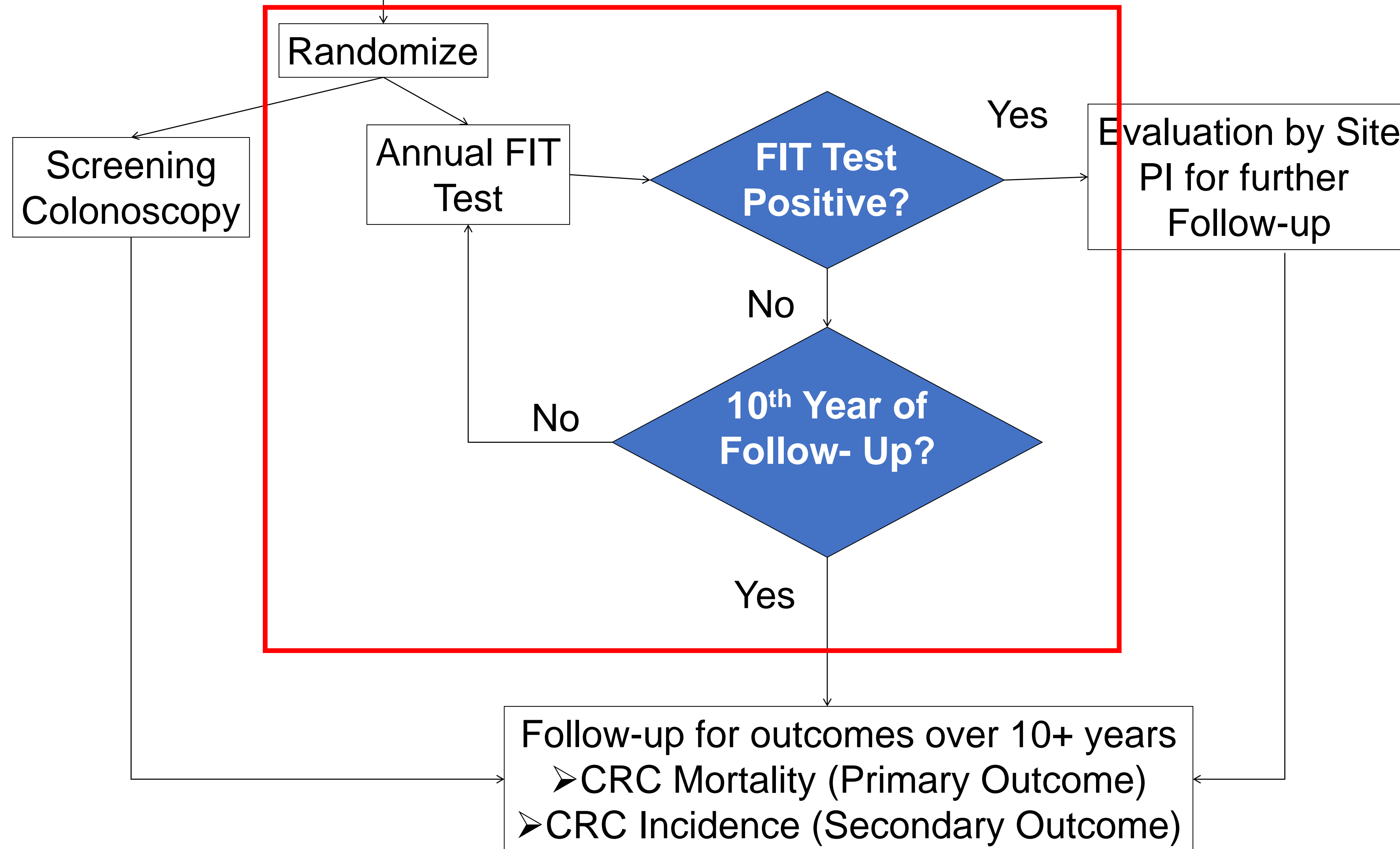




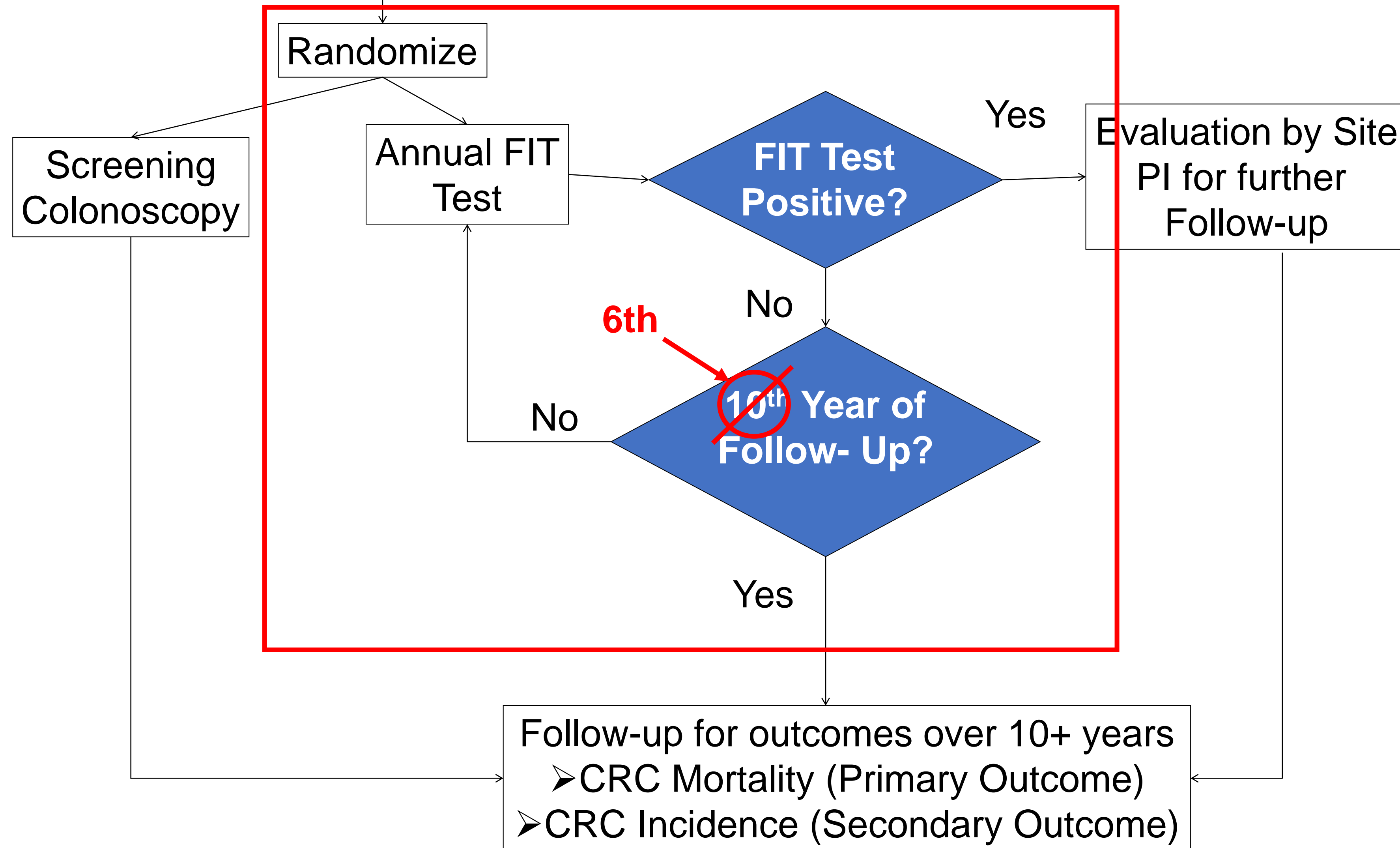




Recruit 50,000 'CRC screen eligible' Veterans (Age 50-75)



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# CONFIRM FIT Screening Process: Baseline

- Upon randomization to FIT:
  - Trained study coordinator delivered verbal FIT instructions
  - FIT provided to participant, with written instructions
- If FIT was not returned within 45 days, a second FIT was mailed



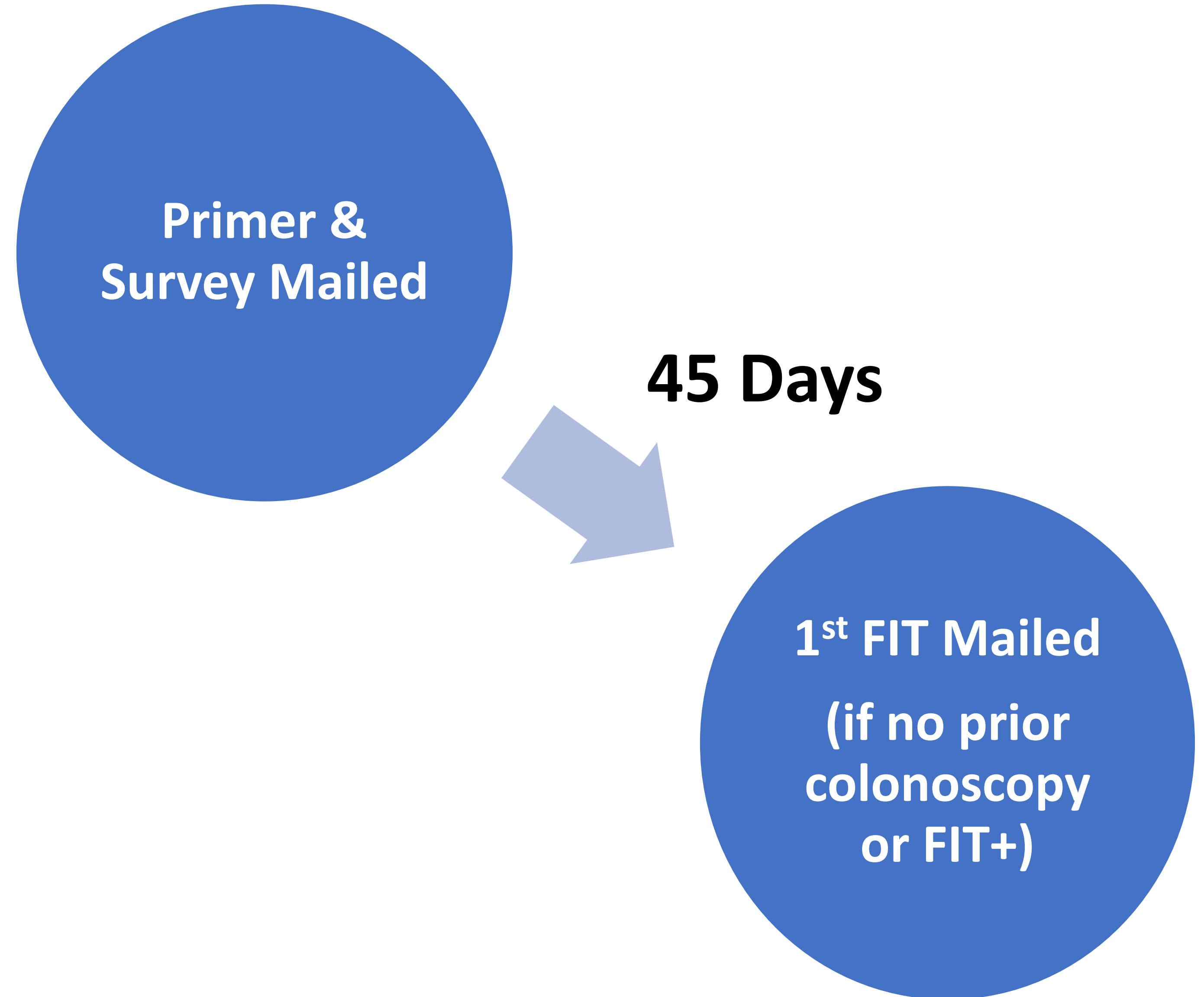
# CONFIRM FIT Screening Process: Rounds 2-6

**10 months after last FIT  
result (or mailing of 1<sup>st</sup>  
FIT, if no result)**

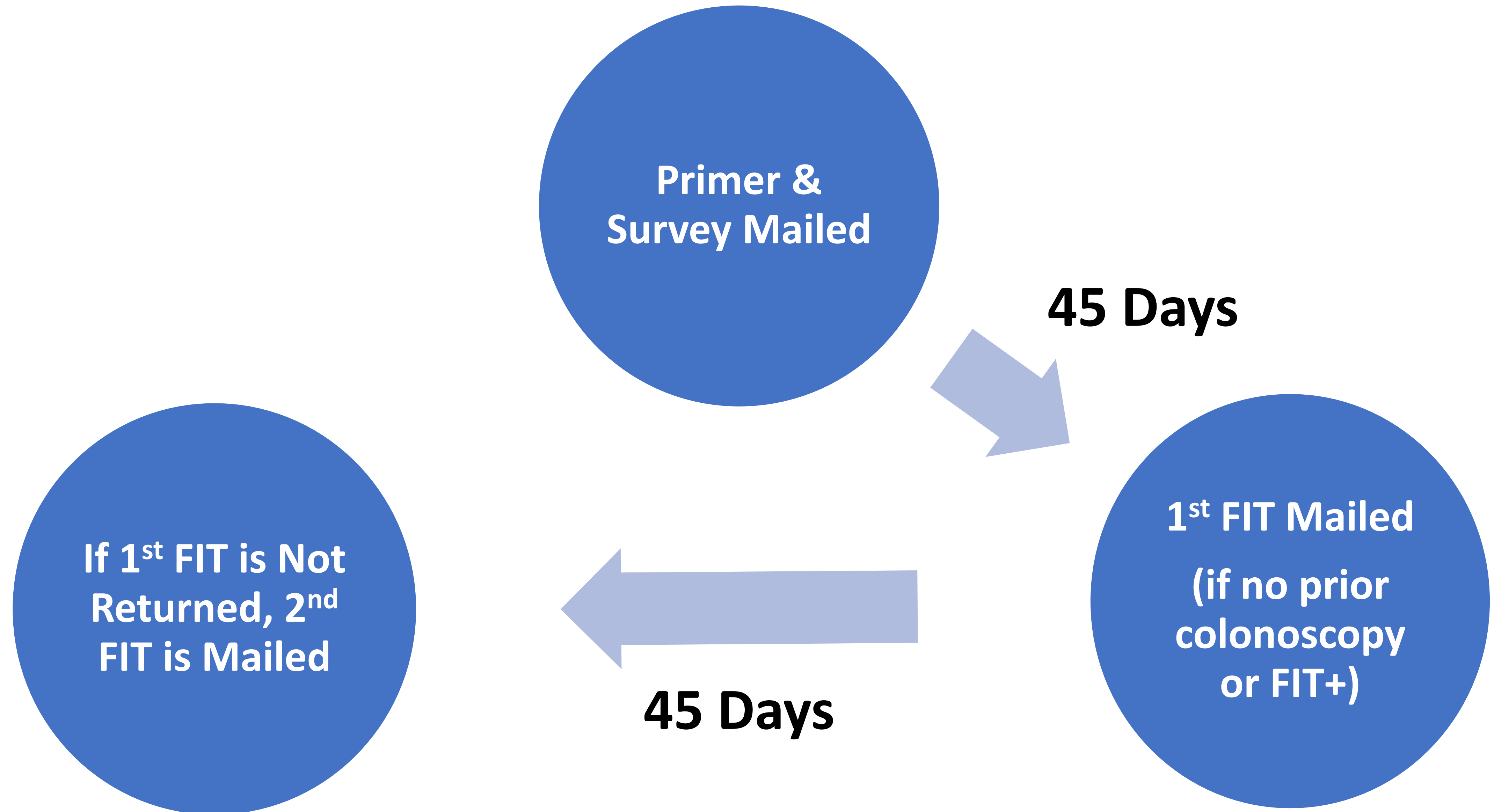


**Primer &  
Survey Mailed**

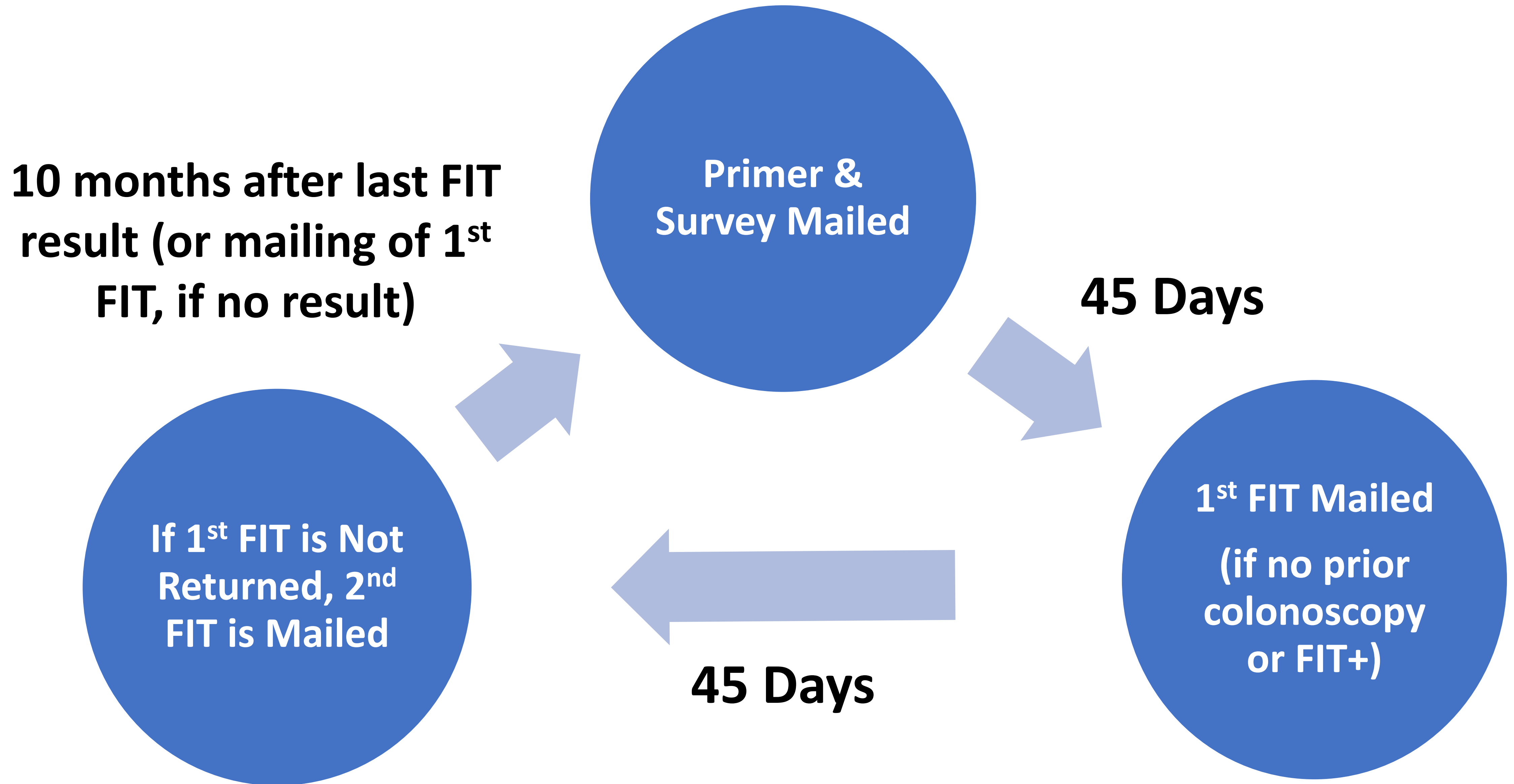
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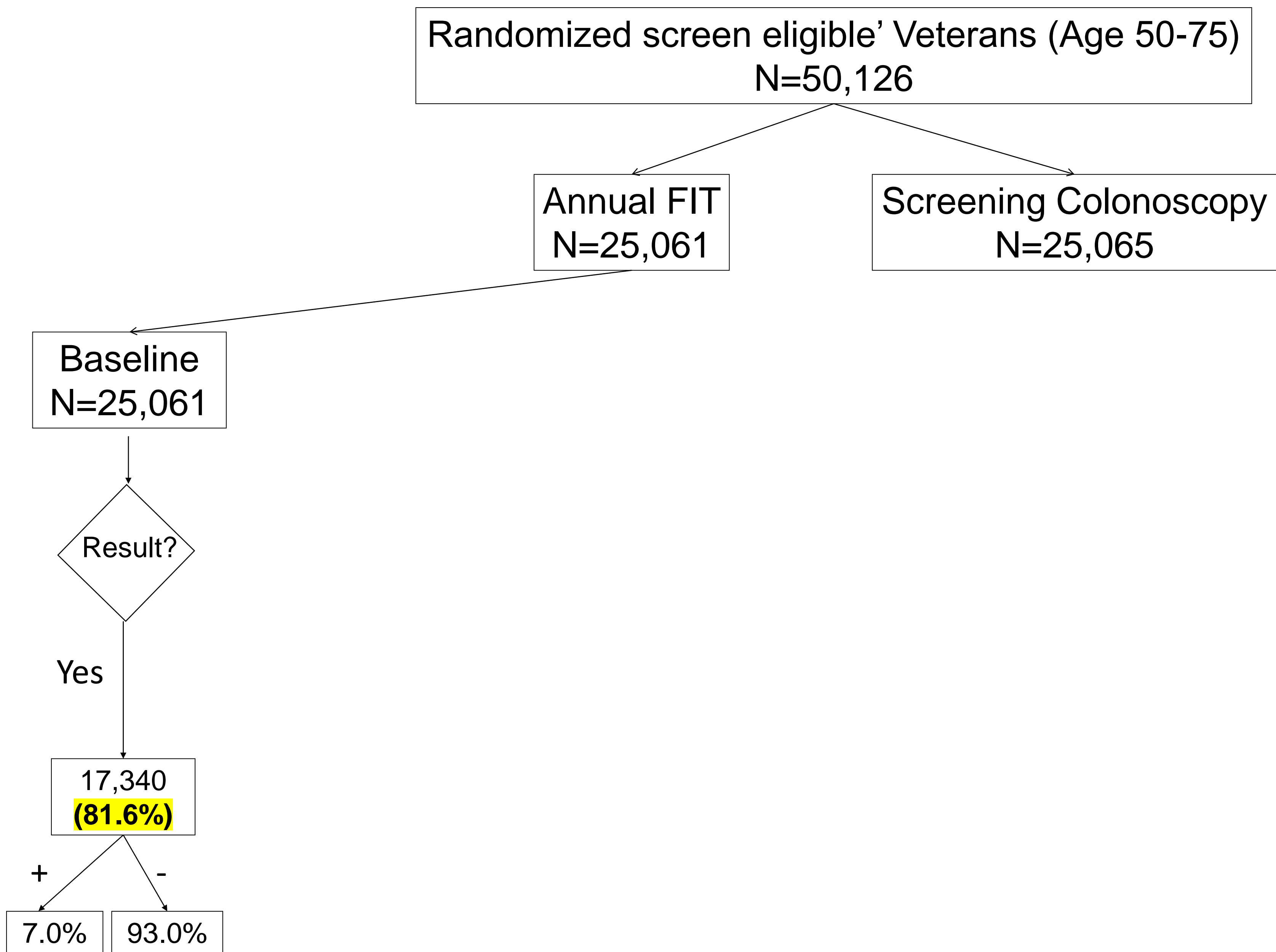


# CONFIRM FIT Screening Process: Rounds 2-6

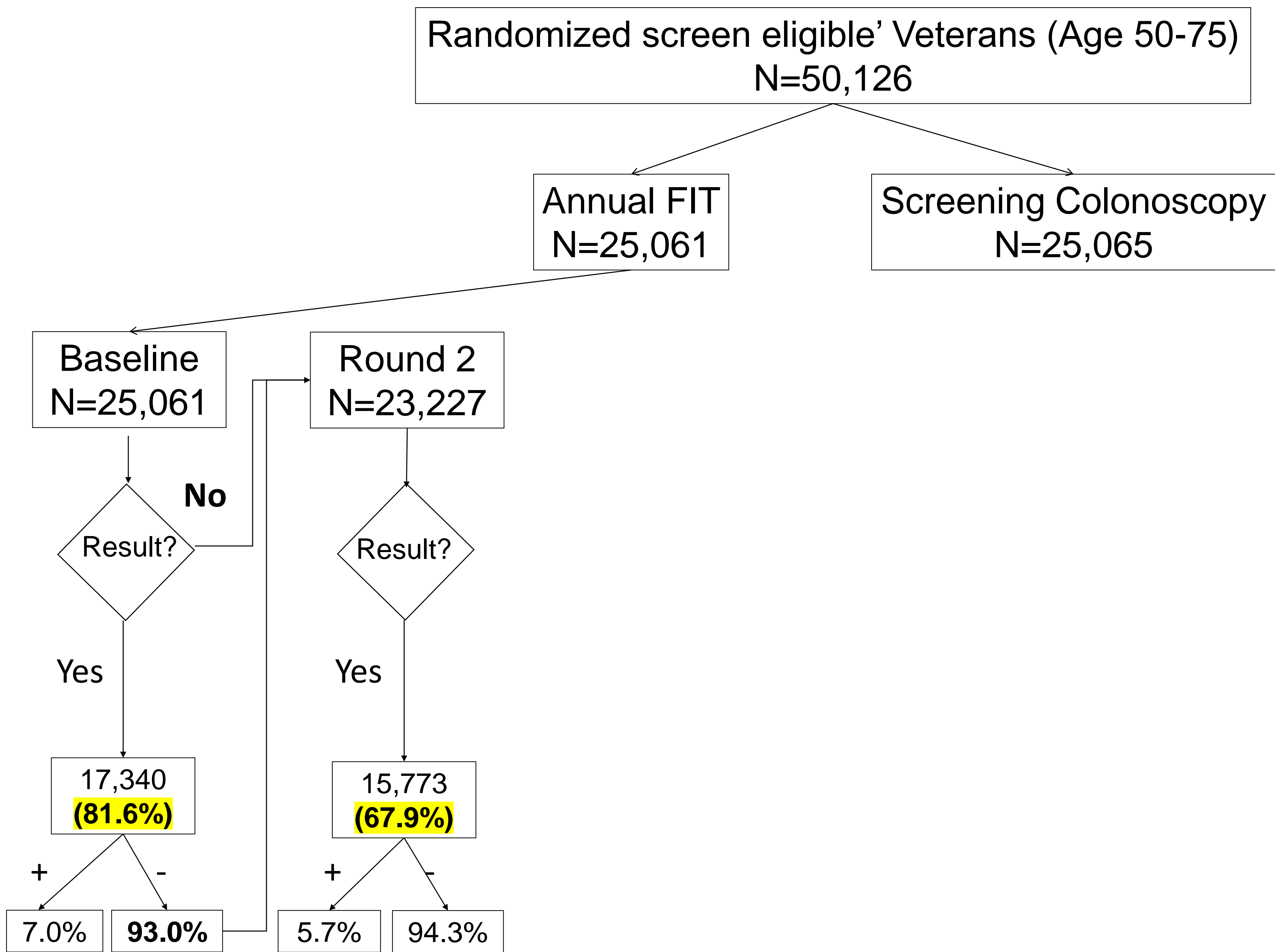


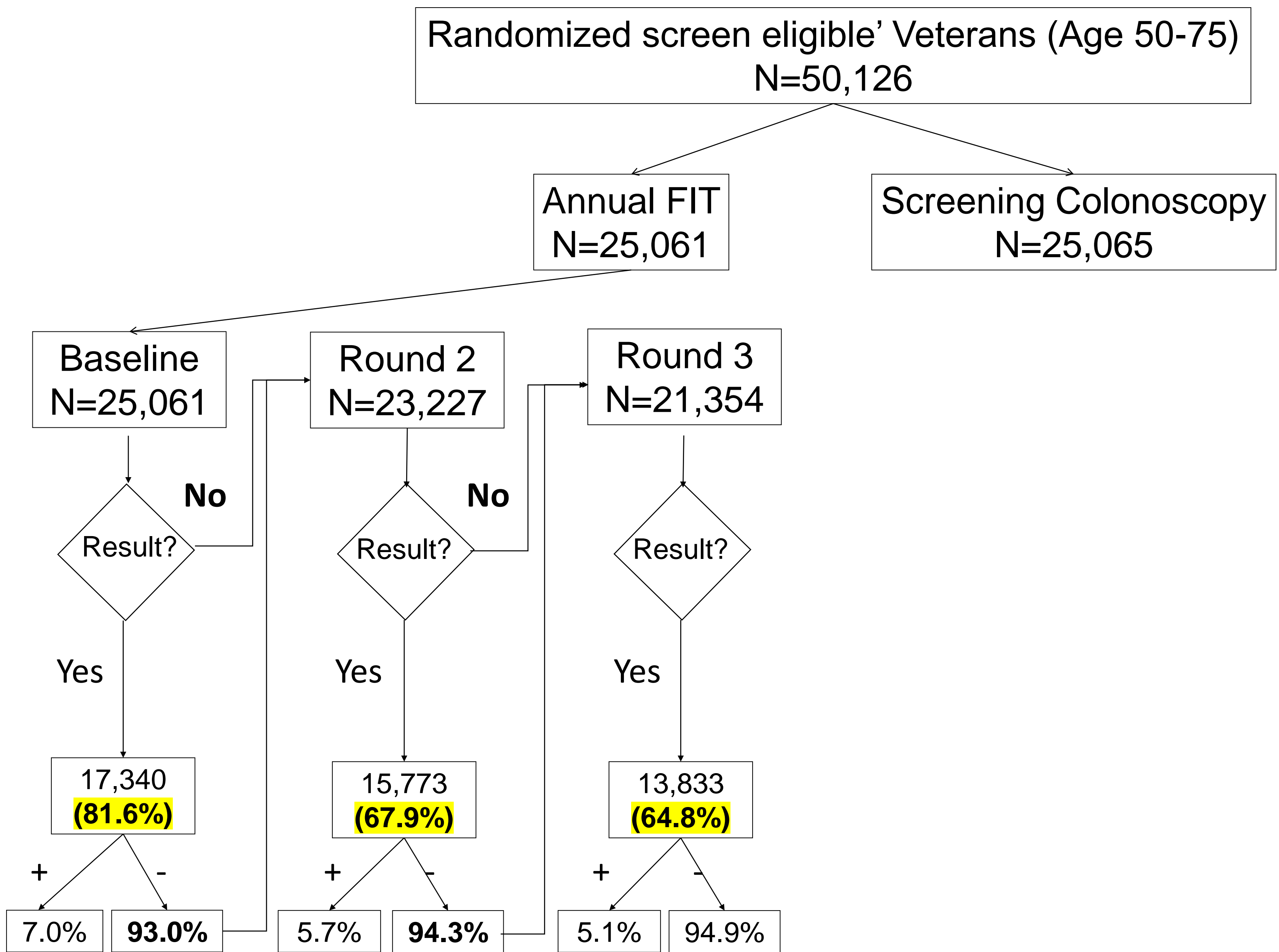
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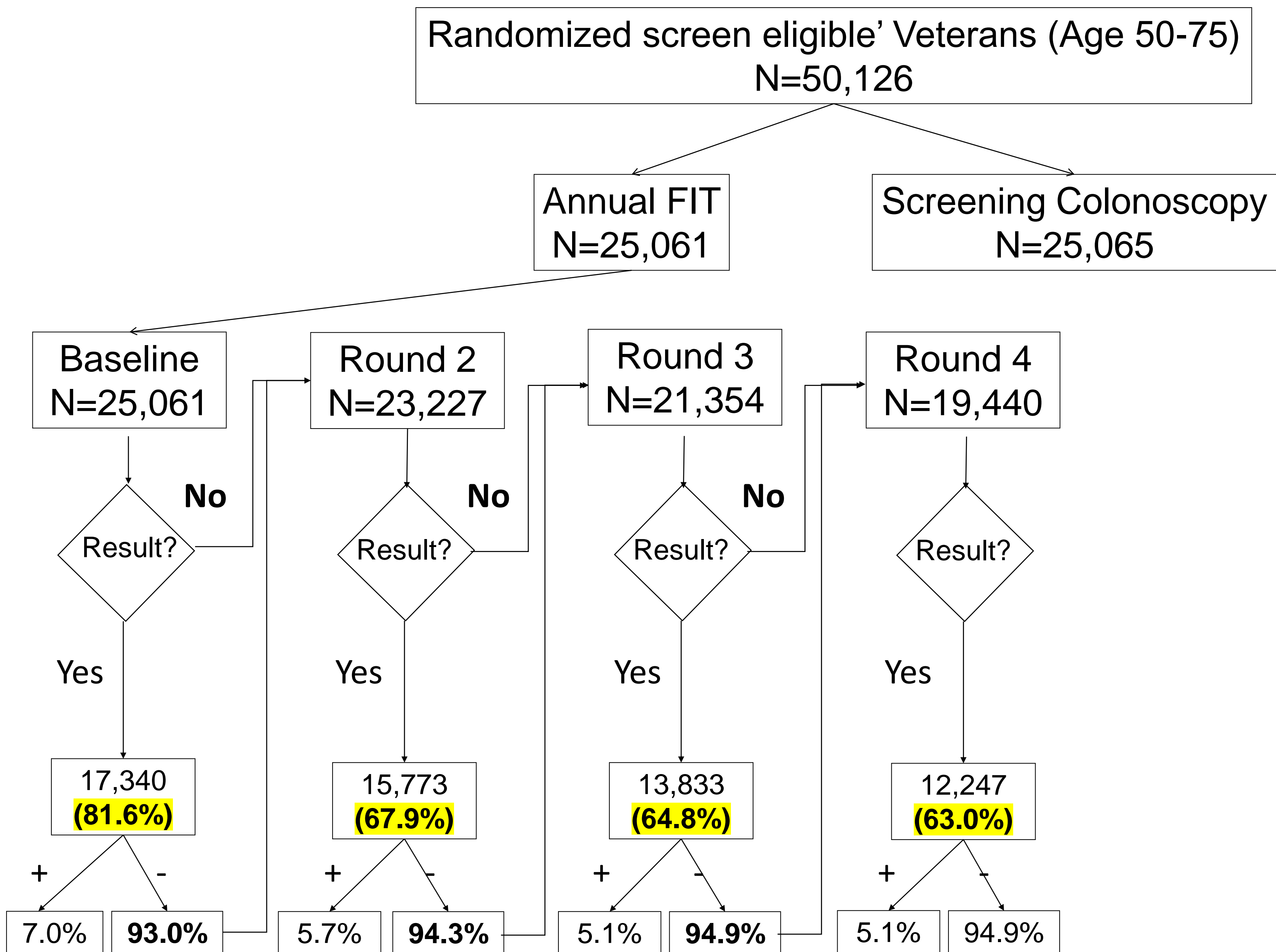


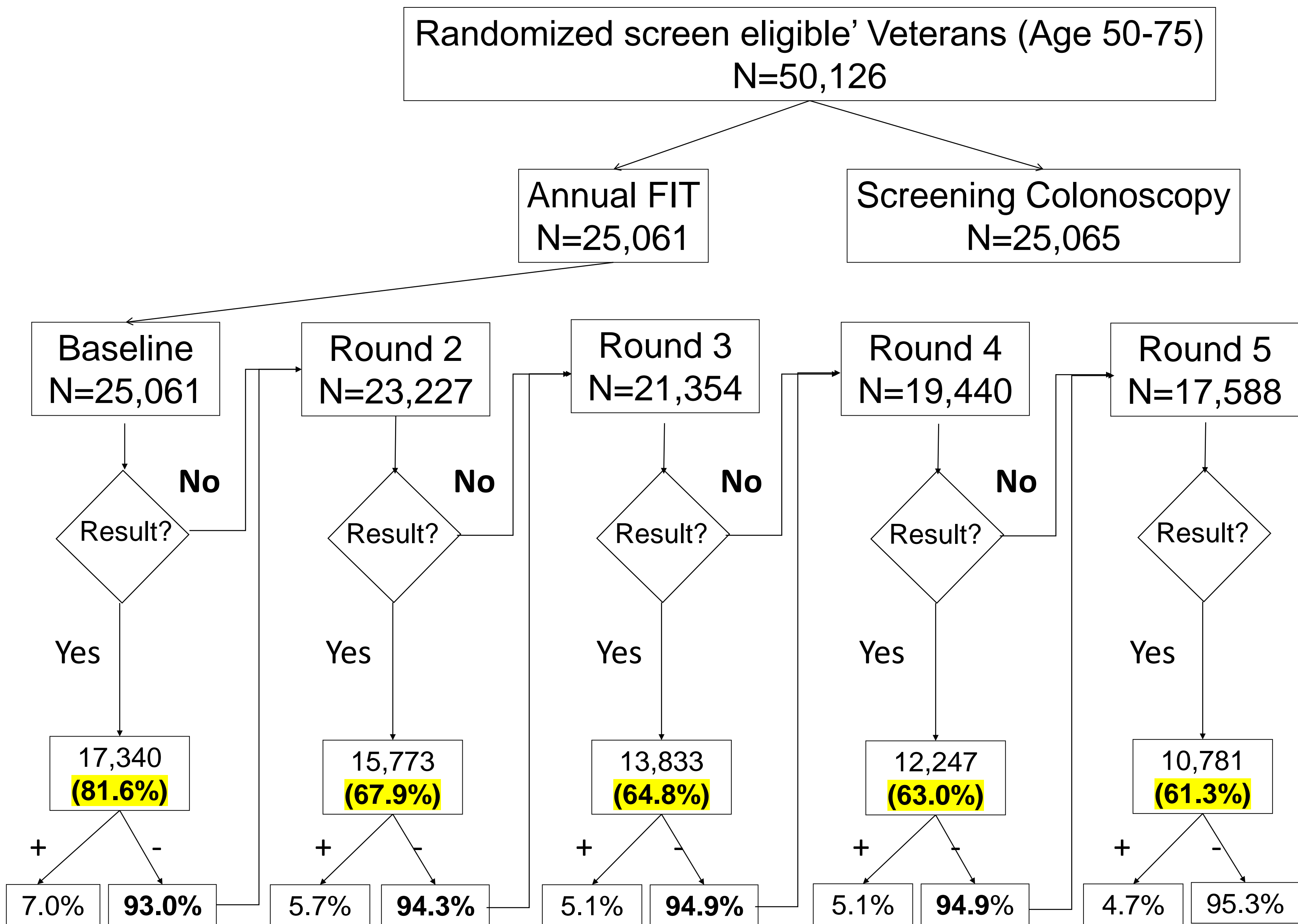


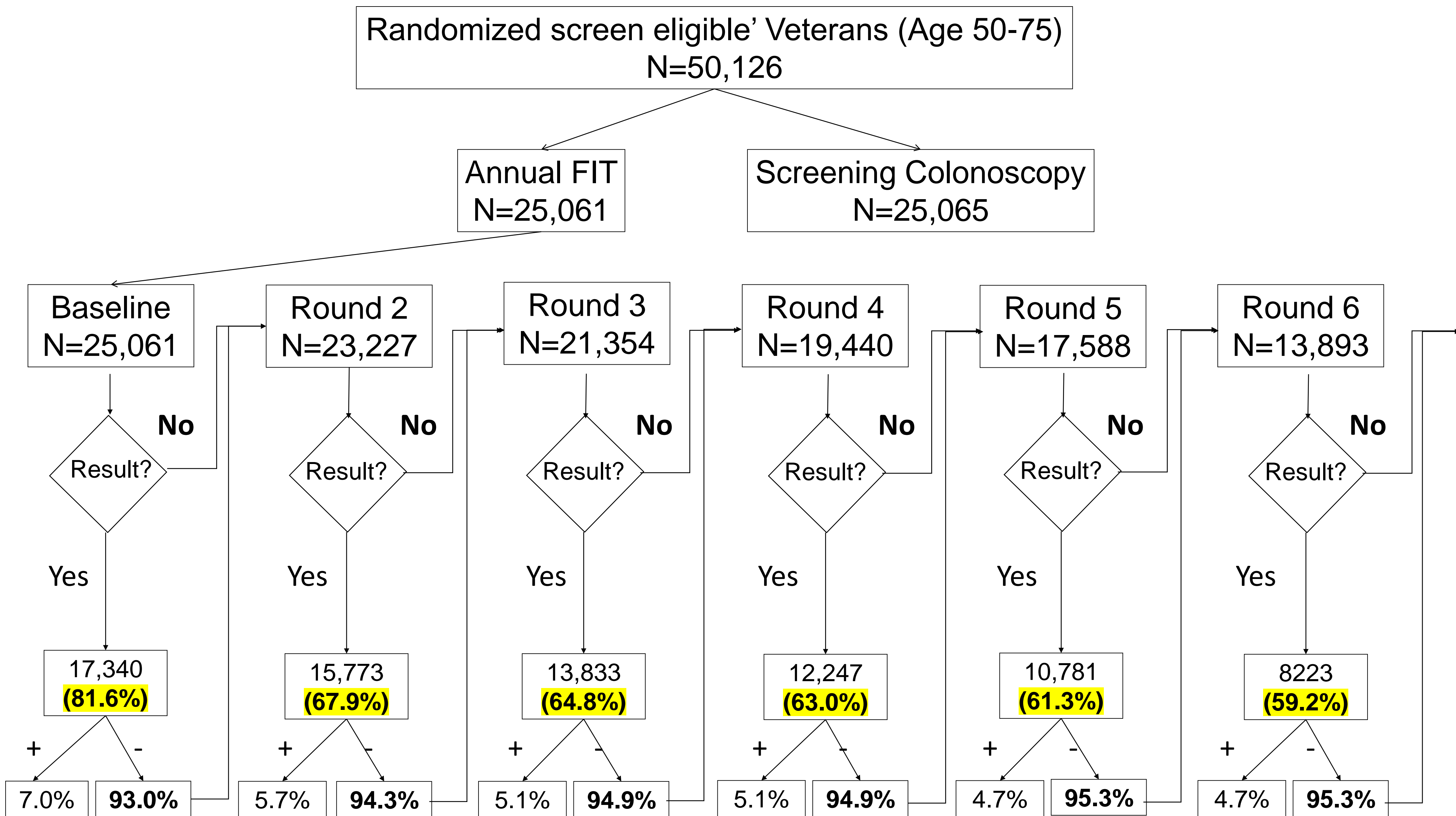














# Results: FIT Adherence

	FIT Completion
Baseline FIT	81.6%
At least 1 FIT (any time)	87.0%
Exactly 1 of 6	10.6%
Exactly 2 of 6	7.6%
Exactly 3 of 6	6.5%
Exactly 4 of 6	7.1%
Exactly 5 of 6	10.7%
<b>ANNUAL FIT (i.e., 6 of 6)</b>	<b>44.5%</b>

Among those eligible for 6 rounds of screening (n=13,893)

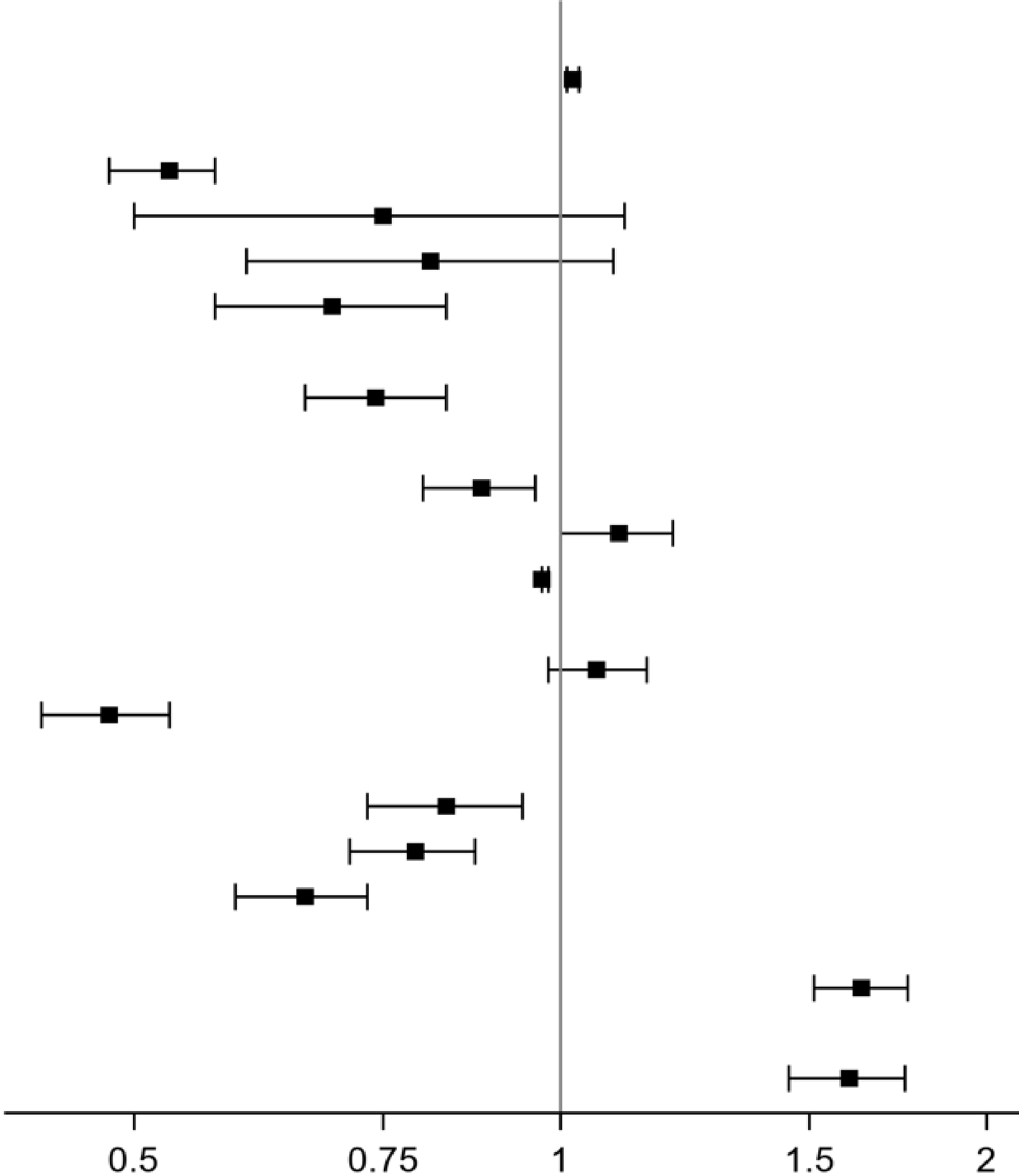
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<b>ANNUAL FIT (i.e., 6 of 6)</b>	<b>44.5%</b>
<b>BIENNIAL FIT</b>	<b>61.1%</b>

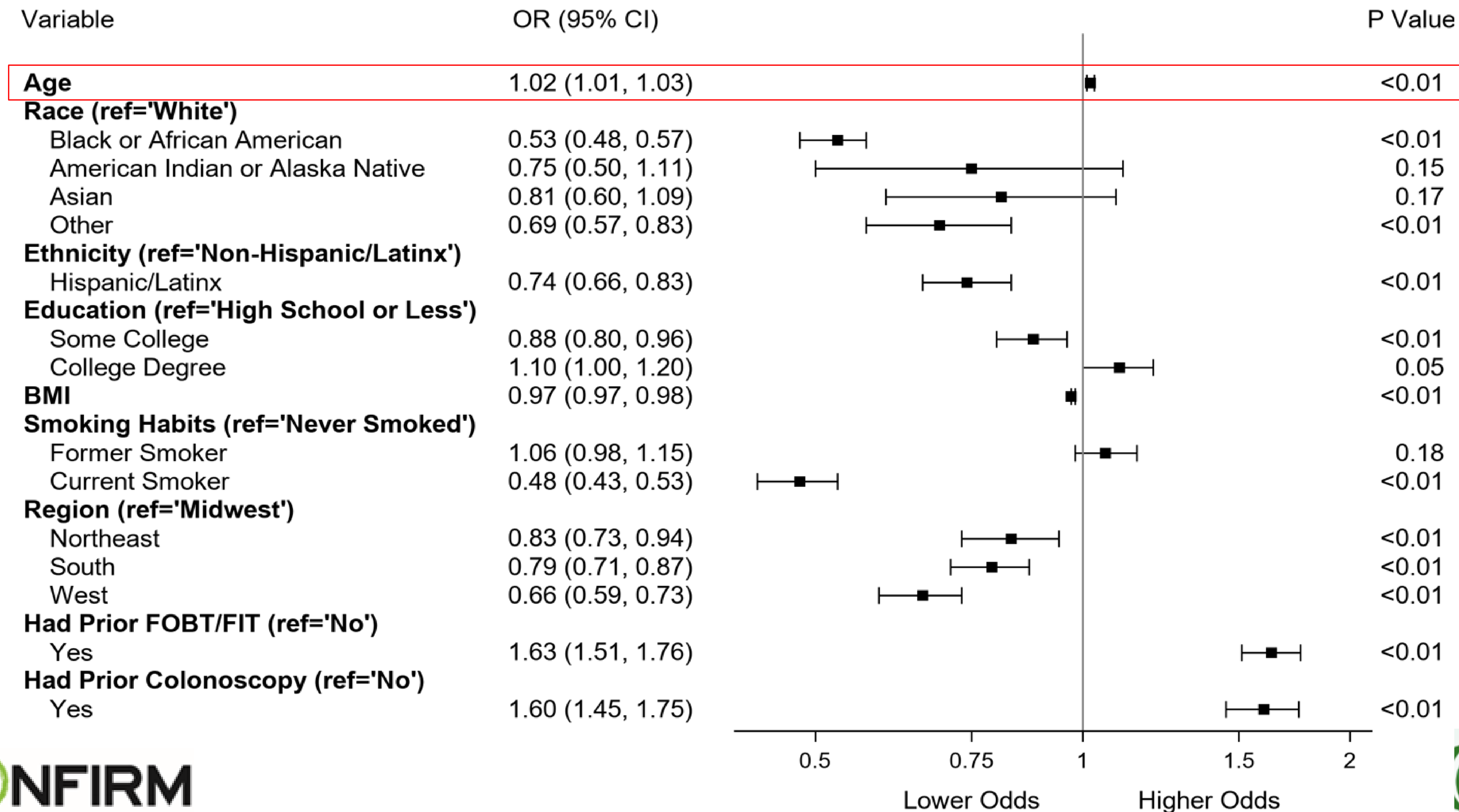
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# Multivariable Predictors of FIT Adherence: Annual

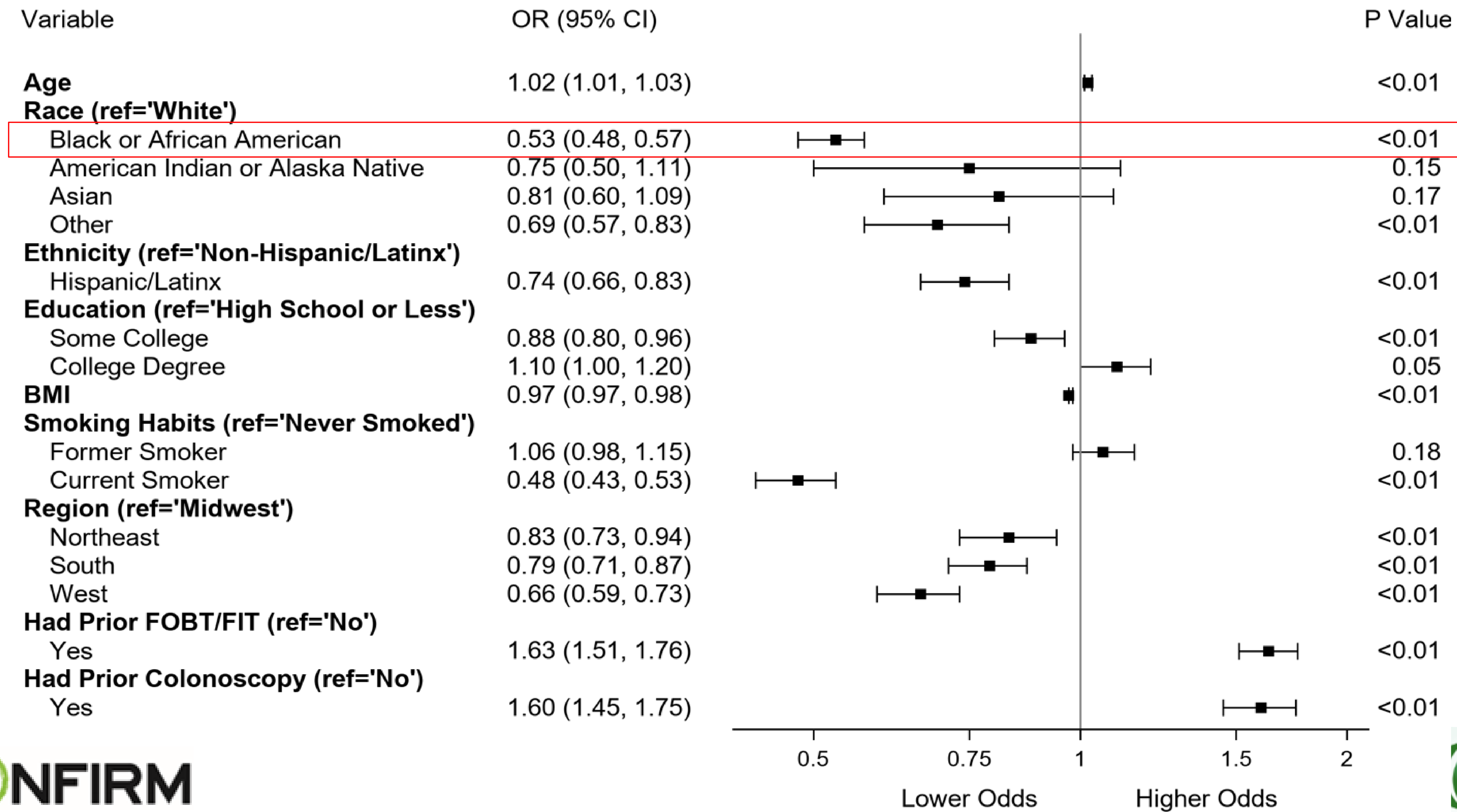
Variable	OR (95% CI)	P Value
<b>Age</b>	1.02 (1.01, 1.03)	<0.01
<b>Race (ref='White')</b>		
Black or African American	0.53 (0.48, 0.57)	<0.01
American Indian or Alaska Native	0.75 (0.50, 1.11)	0.15
Asian	0.81 (0.60, 1.09)	0.17
Other	0.69 (0.57, 0.83)	<0.01
<b>Ethnicity (ref='Non-Hispanic/Latinx')</b>		
Hispanic/Latinx	0.74 (0.66, 0.83)	<0.01
<b>Education (ref='High School or Less')</b>		
Some College	0.88 (0.80, 0.96)	<0.01
College Degree	1.10 (1.00, 1.20)	0.05
<b>BMI</b>	0.97 (0.97, 0.98)	<0.01
<b>Smoking Habits (ref='Never Smoked')</b>		
Former Smoker	1.06 (0.98, 1.15)	0.18
Current Smoker	0.48 (0.43, 0.53)	<0.01
<b>Region (ref='Midwest')</b>		
Northeast	0.83 (0.73, 0.94)	<0.01
South	0.79 (0.71, 0.87)	<0.01
West	0.66 (0.59, 0.73)	<0.01
<b>Had Prior FOBT/FIT (ref='No')</b>		
Yes	1.63 (1.51, 1.76)	<0.01
<b>Had Prior Colonoscopy (ref='No')</b>		
Yes	1.60 (1.45, 1.75)	<0.01



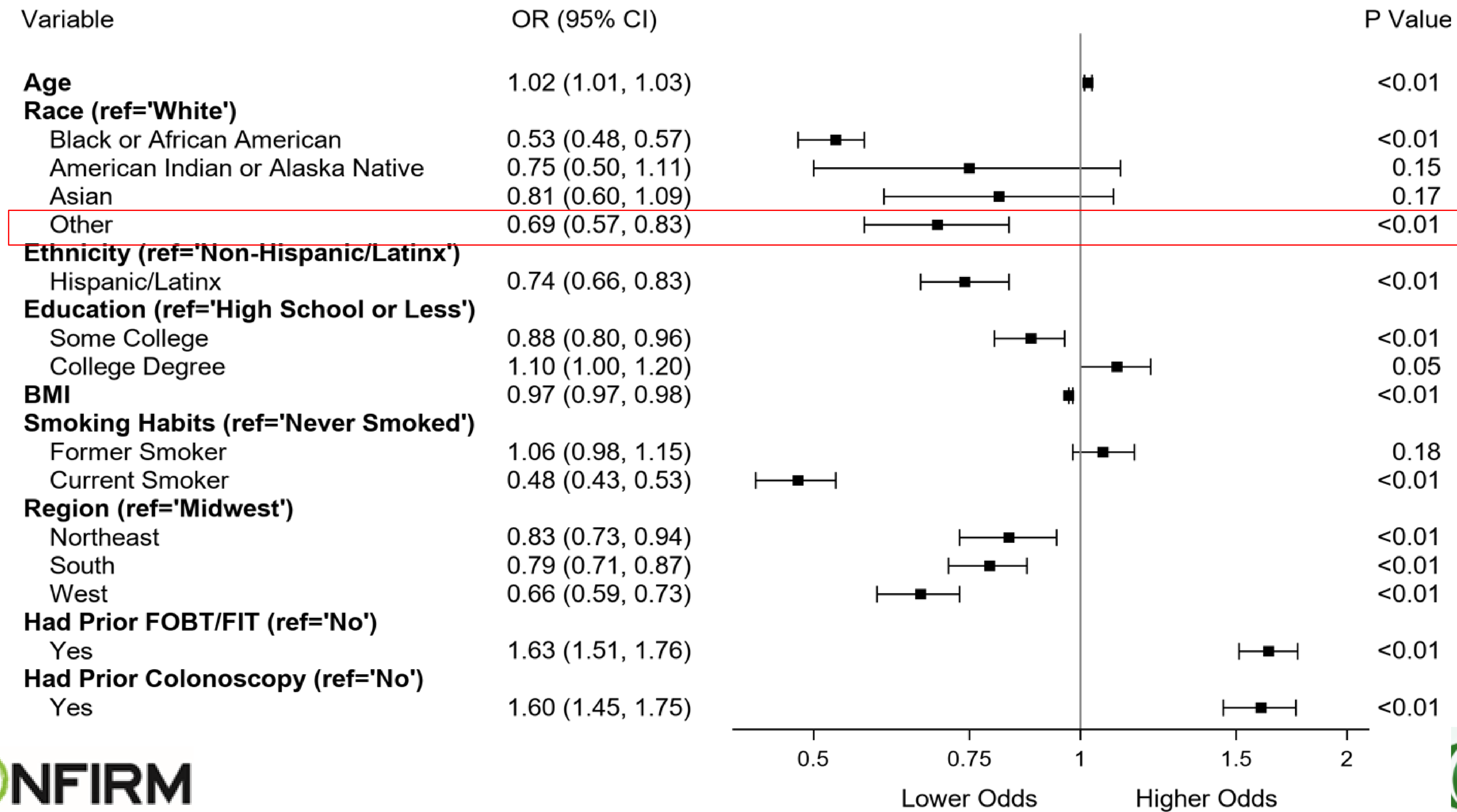
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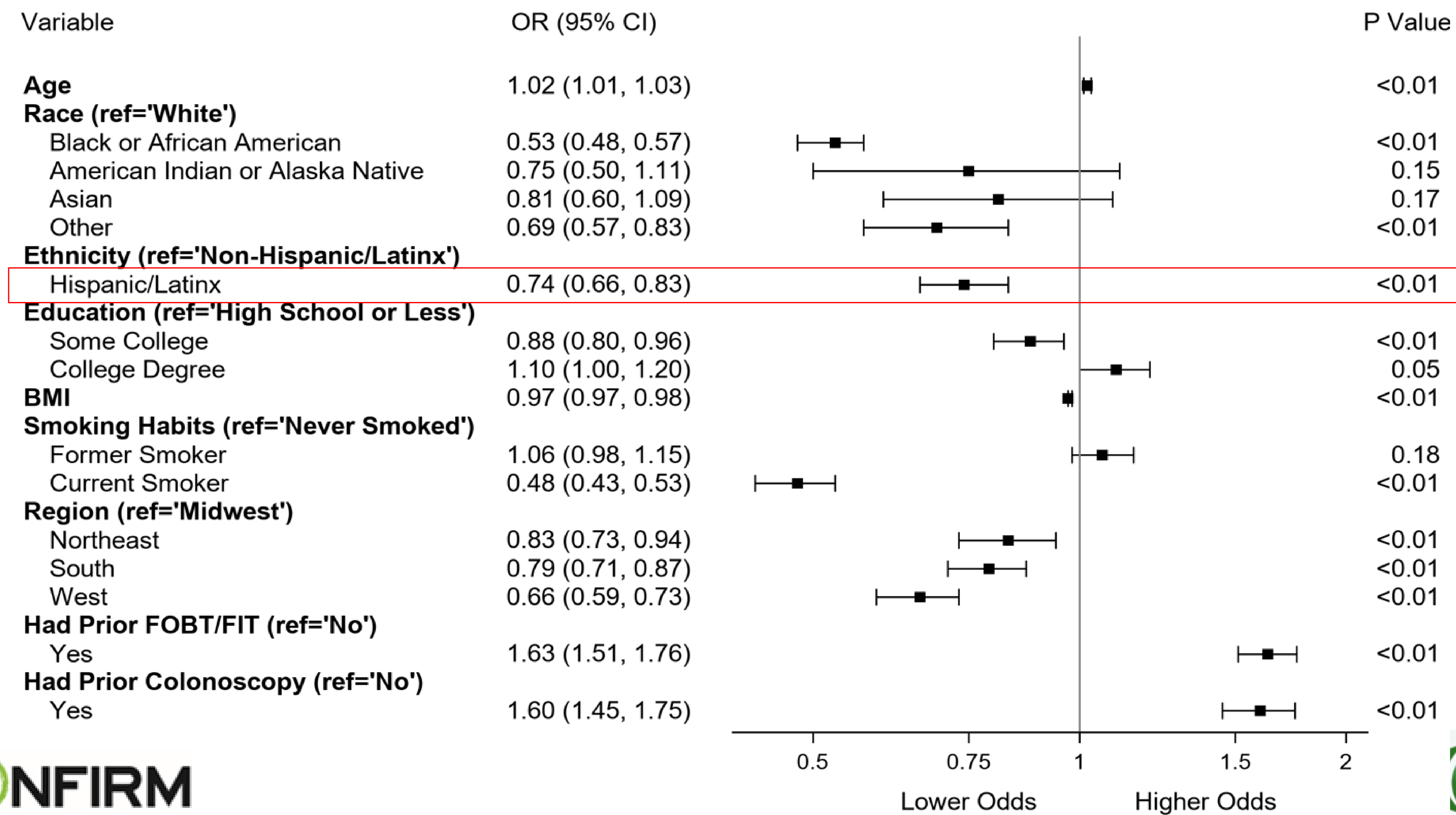


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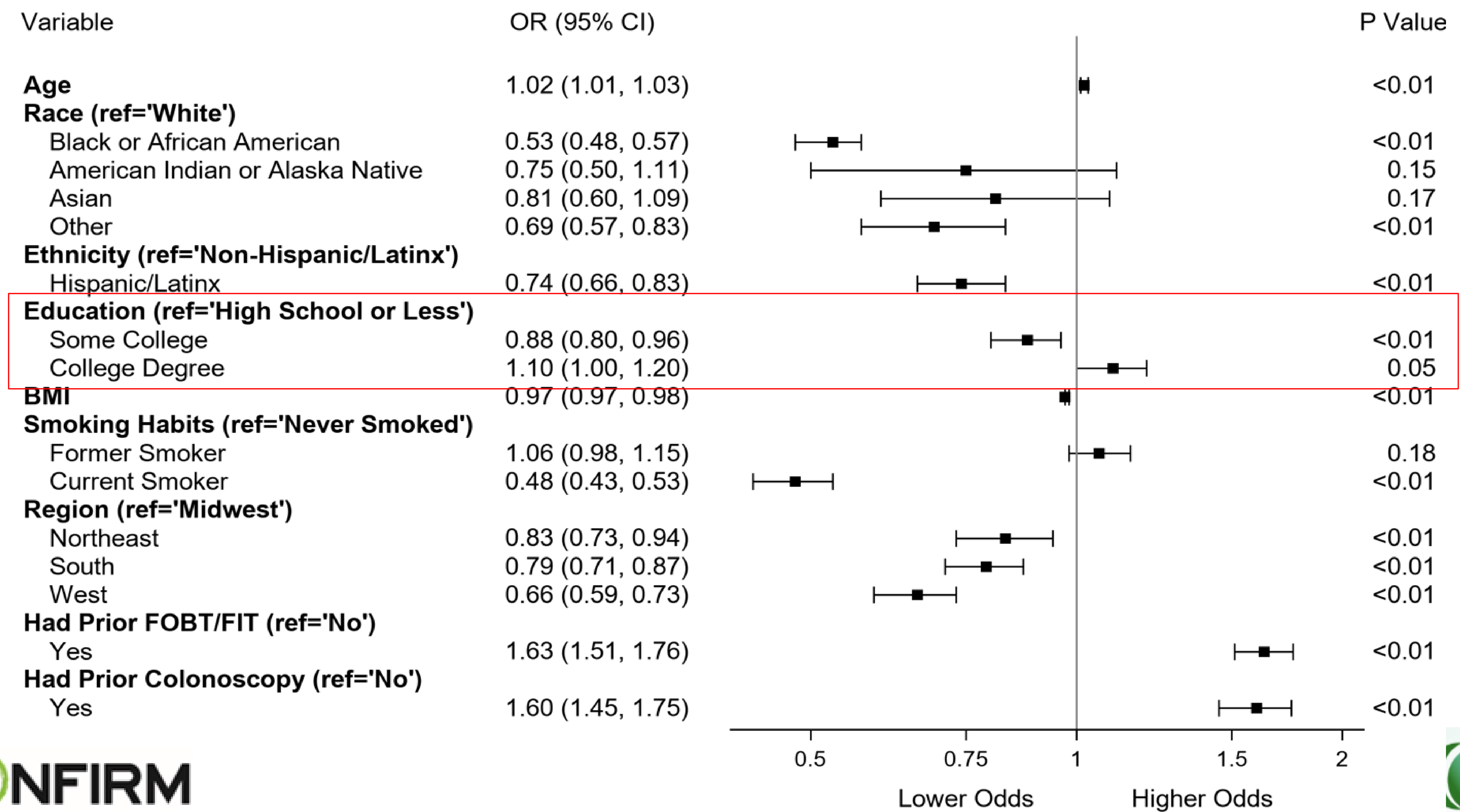




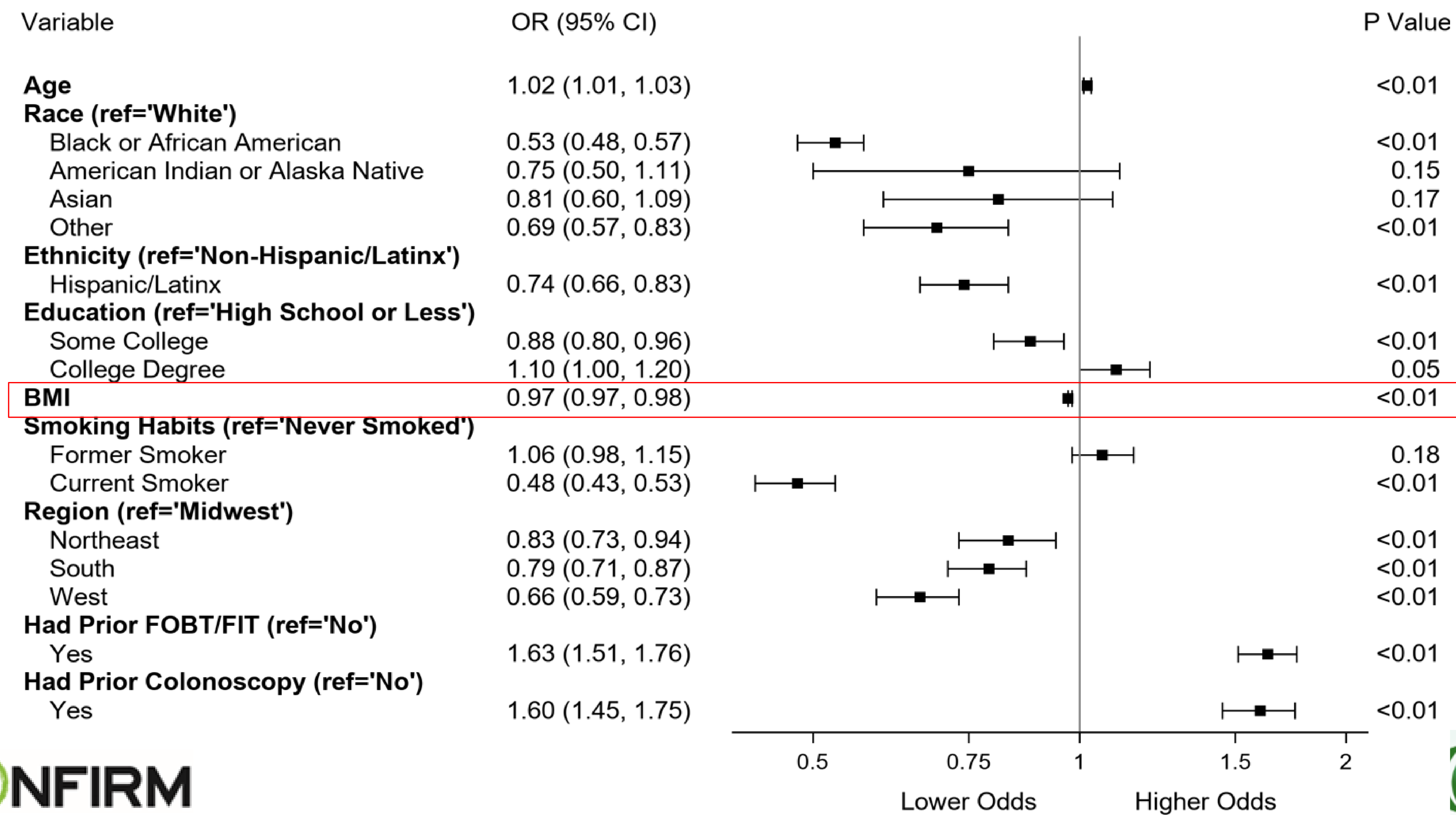
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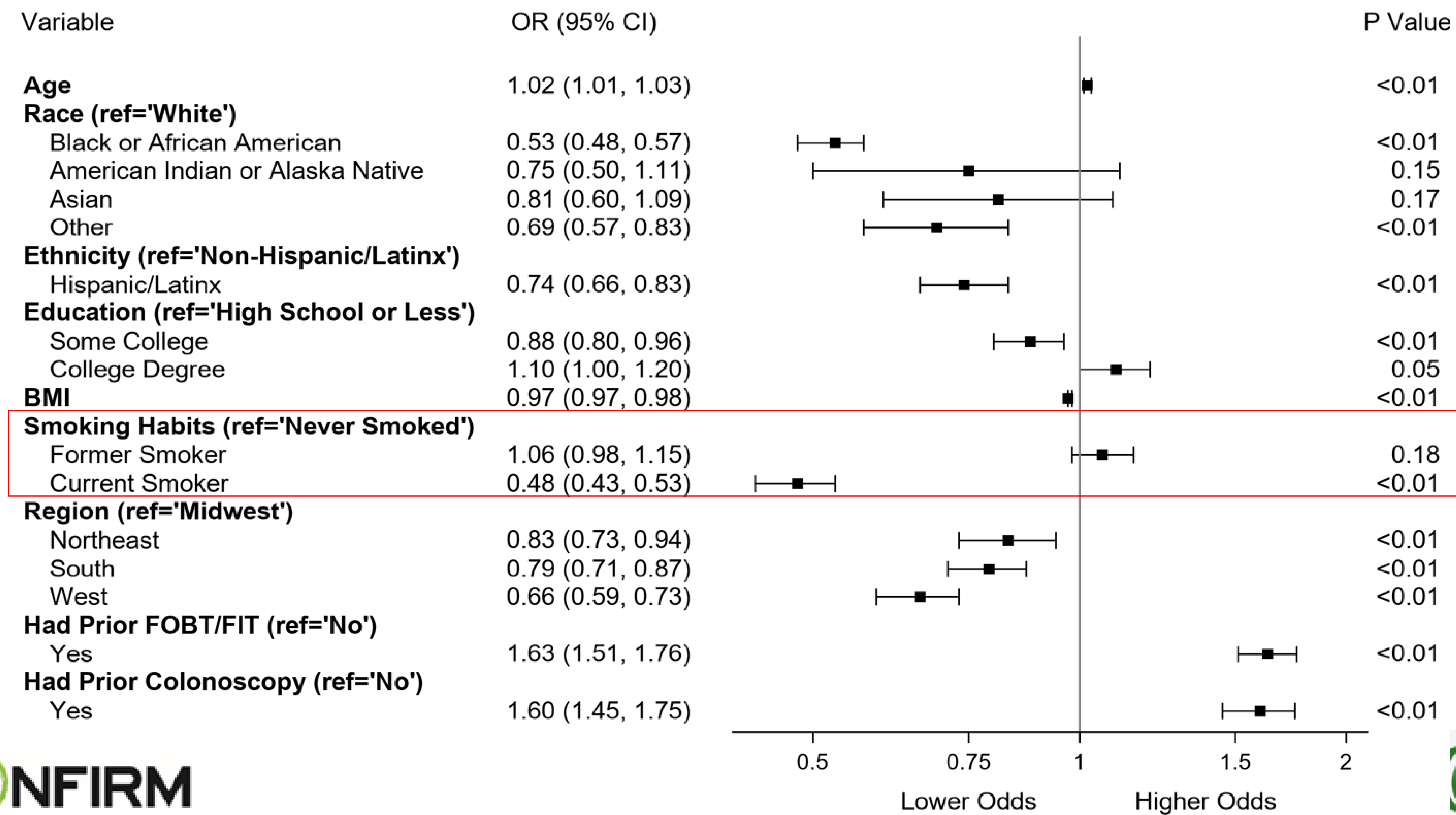
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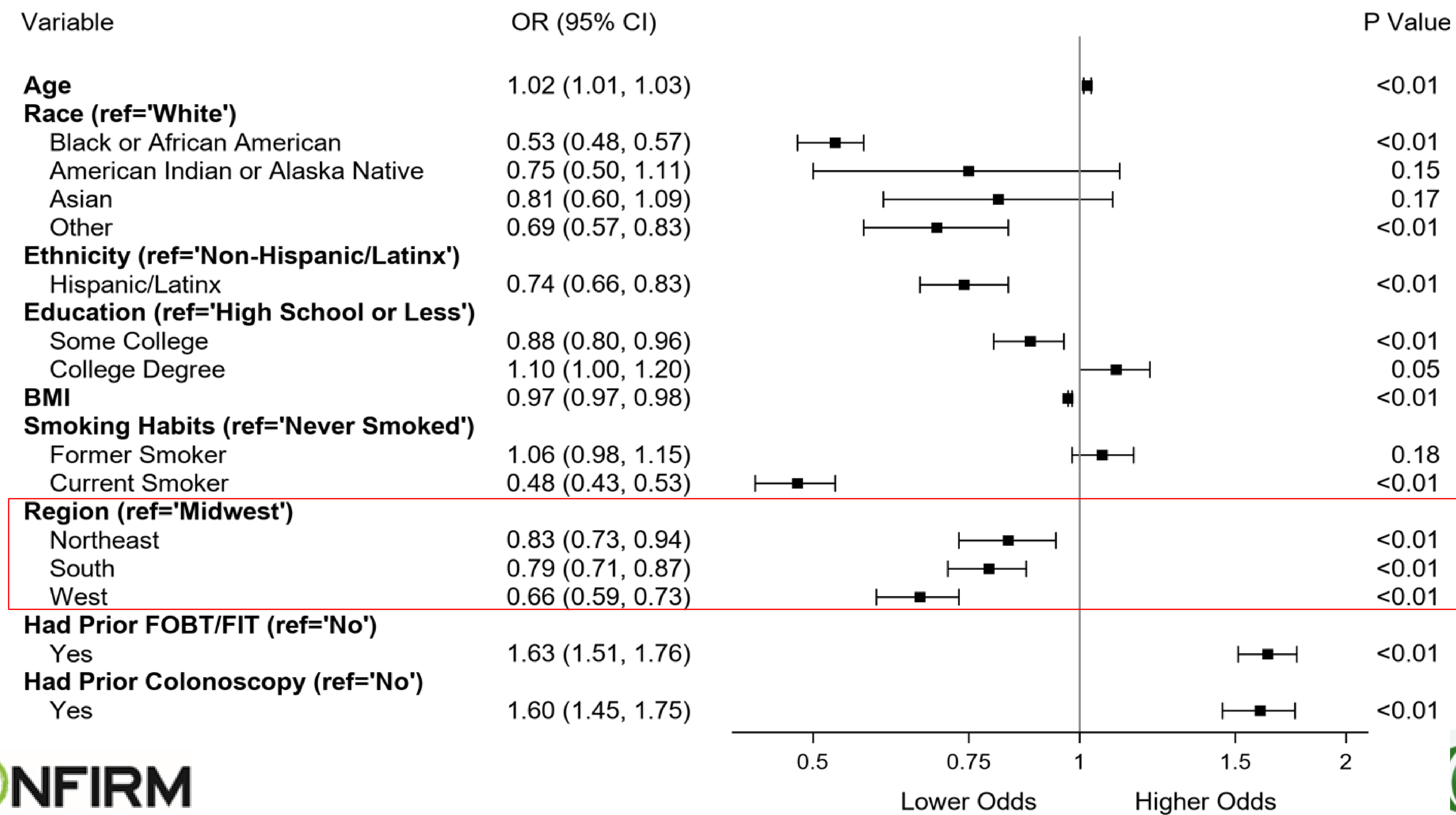
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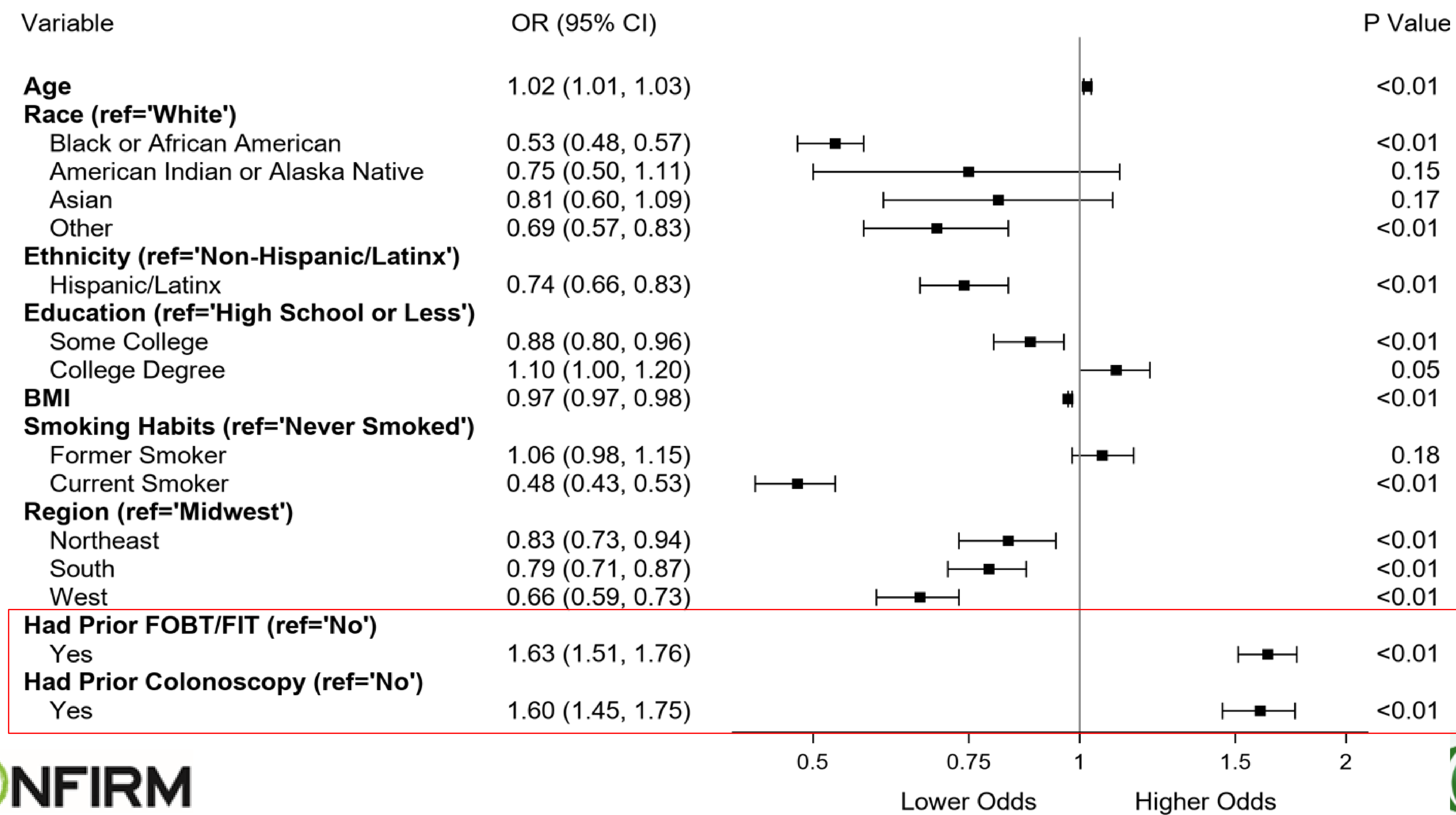
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# Summary

- While FIT adherence was initially high (81.6%), adherence fell to 56%-68%
- Despite annual mailing of FIT, 13% completed no screening
- Another 18.2% completed less than 3 of 6 FIT
- FIT adherence was lower in the following groups:
  - Younger participants, higher BMI
  - Black, other race, Hispanic/Latinx participants
  - American Indian/Alaska Native participants (biennial only)
  - Participants with some college (compared to high school or less)
  - Current tobacco smokers, those without prior FOBT or colonoscopy
  - Northeast, South and West (compared to the Midwest)



# Conclusions

- Ongoing efforts to improve longitudinal FIT adherence are needed
  - especially for those with independent risk factors for non-adherence
- We know that race is a proxy for social determinants of health, but we need to better understand how to mitigate the gaps in FIT adherence
- Tailored strategies may be useful for addressing barriers to adherence
- Future analyses will explore colonoscopy adherence in CONFIRM

# CONFIRM Study Team

## Study Co-Chairs

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