



Colonoscopy vs. stool-based testing
for older adults with a history of colon polyps (COOP
Trial)

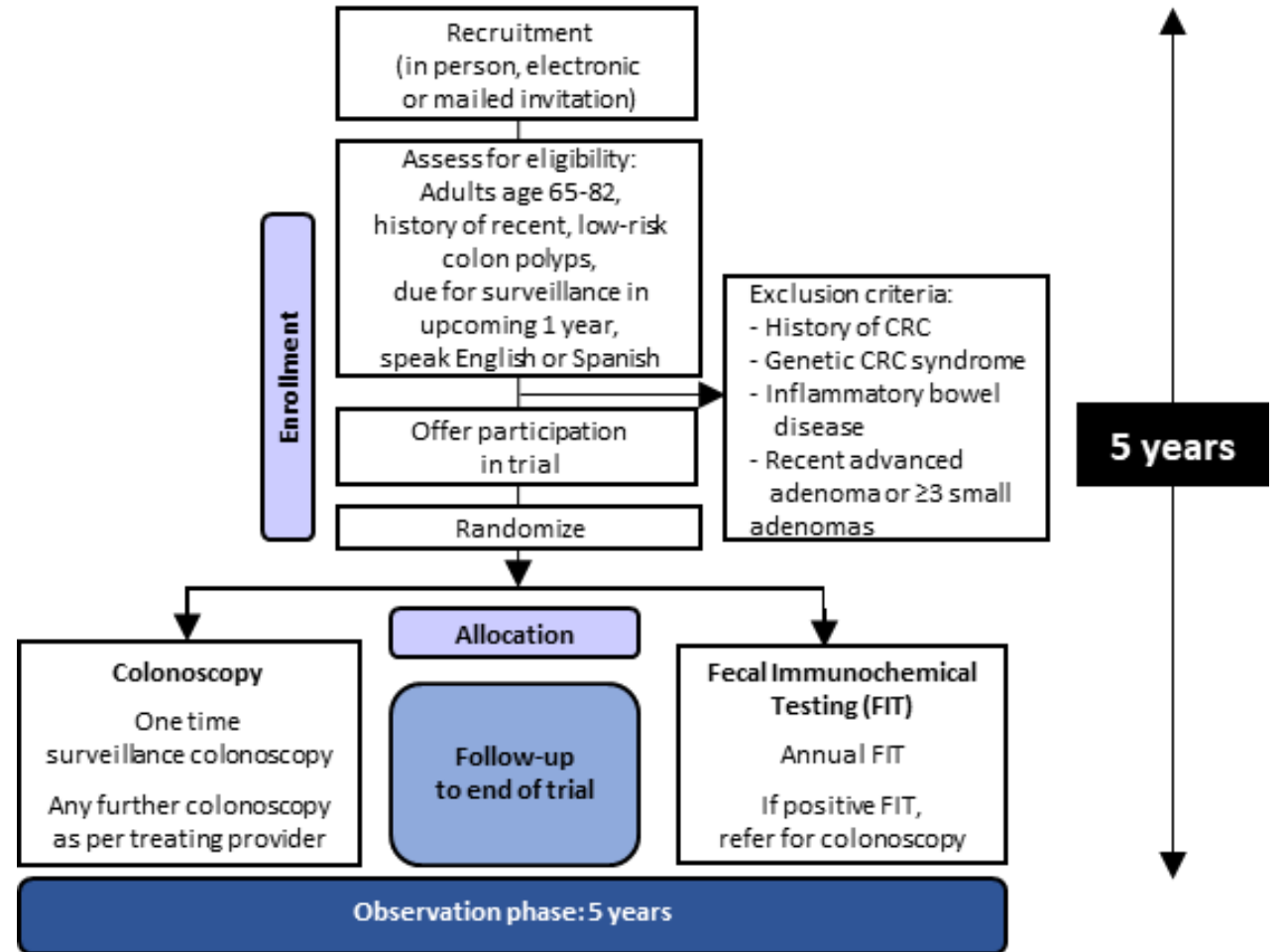
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Study design

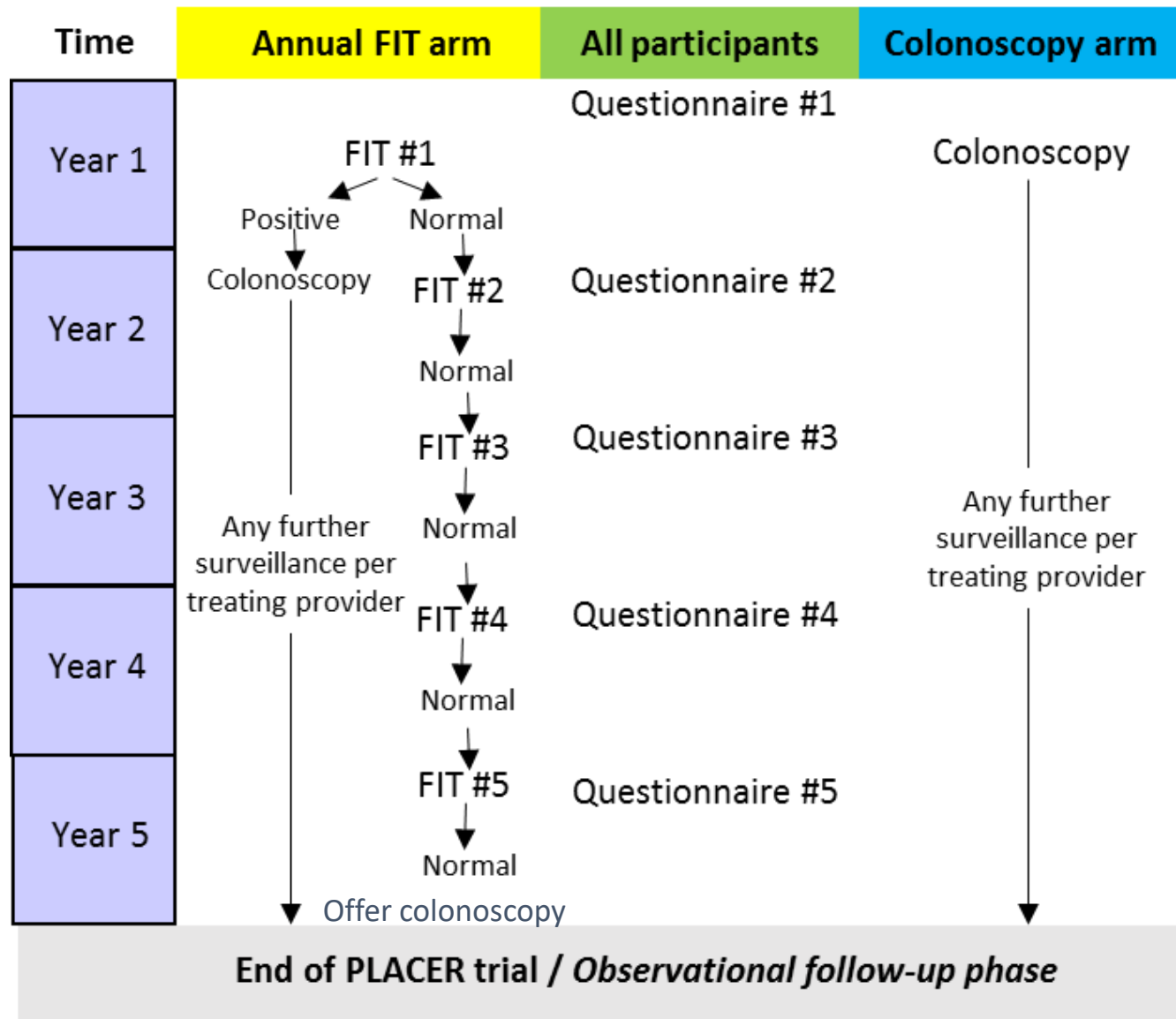
- Three phase, multi-center, prospective, non-inferiority, two-arm, randomized trial
- Comparing the effectiveness of annual FIT vs. colonoscopy
- Allocation 1:1 at the individual level



To compare between study groups:

- Detection of advanced colonic neoplasia
 - CRC
 - Advanced polyps
- Secondary outcomes
 - Patient-reported outcomes and experience measures
 - Patient satisfaction
 - Cancer worry
 - Trust in testing
 - Cumulative risk of harms
- Longer term outcomes
 - CRC incidence
 - CRC mortality
 - All cause mortality

Participant Activities



INCLUSION CRITERIA, REVISED

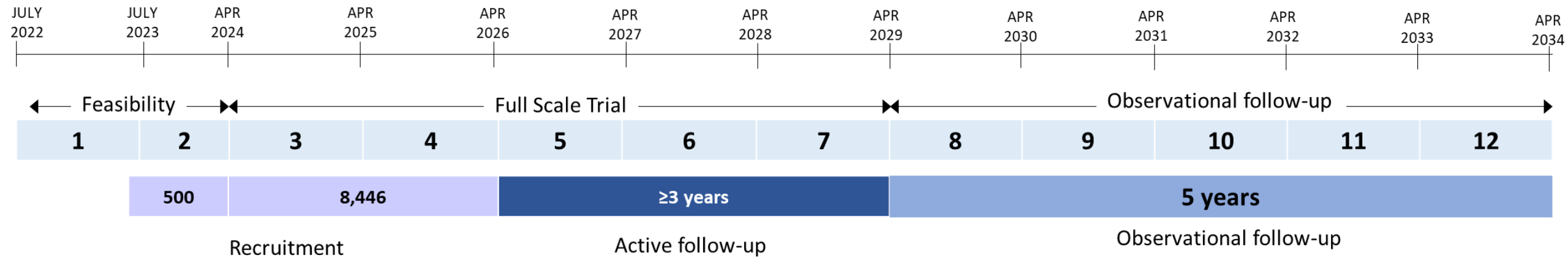
- **Age 65-82**
- Personal history of colon polyps
- Most recent colonoscopy with ≤ 2 non-advanced adenomas
- Due or becoming due for surveillance within 12 months
- English or Spanish speaking
- Able to provide informed consent

EXCLUSION CRITERIA

- Personal history of CRC, genetic CRC syndrome, IBD
- Most recent colonoscopy
 - Advanced adenoma(s) or advanced serrated polyps
 - ≥ 3 non-advanced adenomas
- Unlikely to benefit from surveillance (e.g., poor overall health, advanced dementia, or high risk for colonoscopy)

Timeline

Start of
full scale trial



Reasons

Reasons Ineligible: n = 9412

- Not English or Spanish speaking: ~241
- Significant co-morbidities: ~2063
- H/o CRC: ~523
- Inflammatory bowel disease: ~857
- Lynch syndrome/ FAP: ~48
- Lack of valid mailing address: ~98
- 3-4 Adenomas on most recent colonoscopy (n=1775)
- Polyp history (i.e. no history of polyps *or* most recent colonoscopy with advanced polyp(s) or ≥ 5 small adenomas): ~5582
- Physician Advised against it

Reasons for Declining (n = 1802)

- Prefer FIT (n=82)
- Prefer colonoscopy (n=534)
- Not planning any surveillance (n=113)
- Time commitment (n=144)
- Length of trial (n=17)
- Privacy concerns (n=10)
- Does not want to be part of a study (n=411)
- Did not say (n=292)
- Geography: (n=56)
- Transportation constraints: (n=13)
- Insurance concerns: (n=20)
- Language barrier: (n=5)

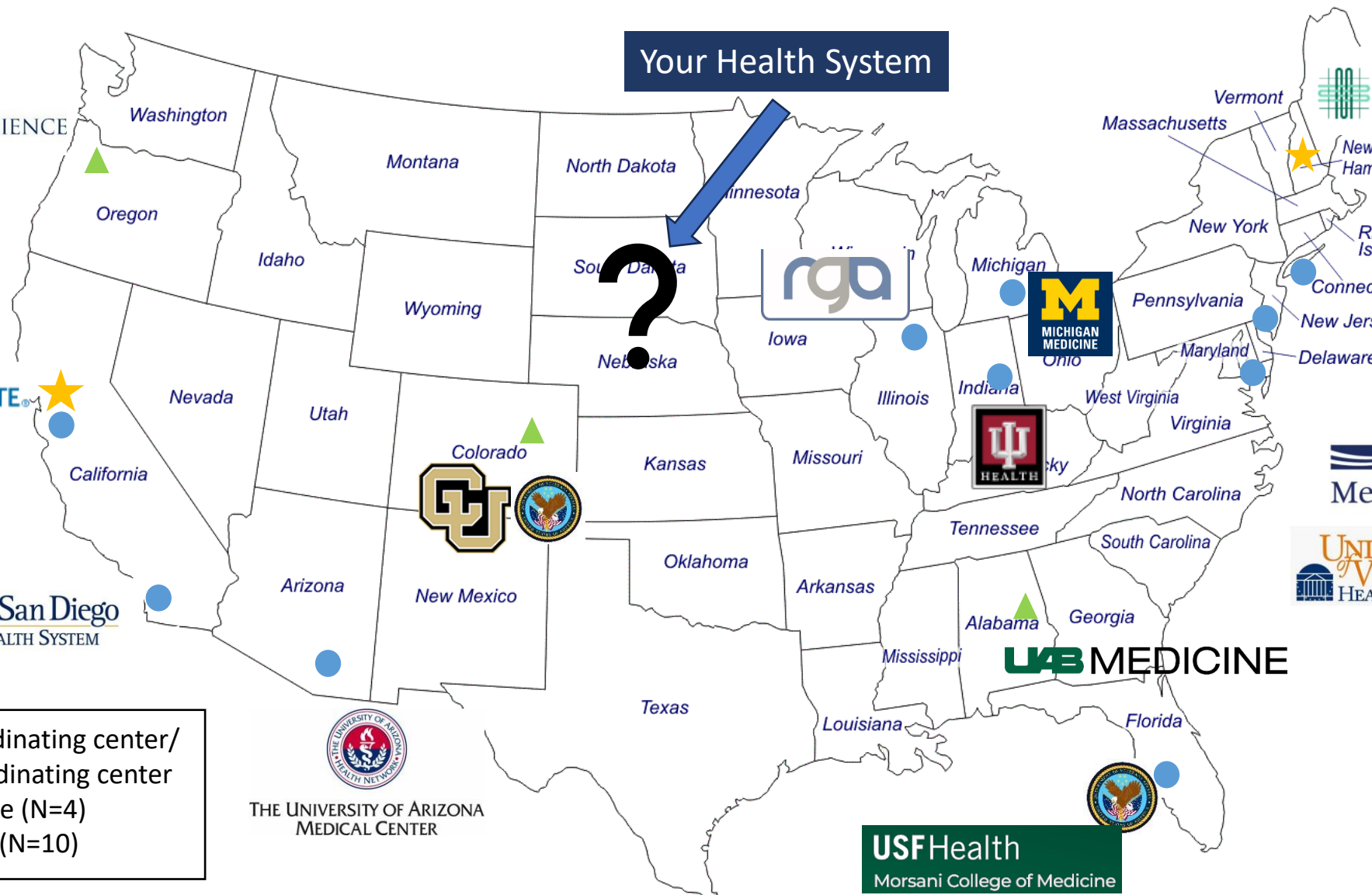
Recruitment

- Chart review for Eligibility
- 30-40% of people are found to be eligible
- 13-15% enroll

- Letters sent: 4368, follow up phone call: 4226
- Enrolled/consented: n = 587

Full scale study sites

Your Health System



- Clinical coordinating center/
Data coordinating center
- Feasibility site (N=4)
- Full trial site (N=10)

Feasibility Phase Lessons Learned: Data Coordinating Center

- IRB approval
- REDCap database development
- Technology Risk Appraisal

Feasibility phase lessons learned: CCC

- Recruitment uptake/effort
- Importance of PCP input
- Eligibility criteria
- Site variability
- Components of successful site
- Central IRB
- Payment model

PRO/PREM

Development of Patient-Reported Outcomes and Measures for Surveillance Colonoscopy

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Background

- Patient-reported outcome (PROs) and patient-reported experience measures (PREMs) are essential in assessing outcomes important for patients in comparative effectiveness research
- The COOP Study compares FIT to colonoscopy for surveillance in older adults with a history of colon polyps
- Primary outcome: cumulative detection rate of advanced colonic neoplasia over 5 years
- Secondary outcome: focuses on PROs and PREMs capturing patient perceptions and experiences
- There is a need for a validated instrument to assess PROs and PREMs related to polyp surveillance testing

Methods

- 1 Literature review**
To identify potential PRO/PREMs focused on CRC screening screening and surveillance
- 2 Patient and physician interviews**
To gather insights on important factors related to surveillance. Coded using qualitative analysis program
- 3 Creating draft instrument**
New PRO/PREM instrument drafted based on key domains and topics identified through analysis of interview data
- 4 Cognitive interviews**
With older adults to identify items that caused confusion, were unclear, or required different answer options
- 5 Final instrument**

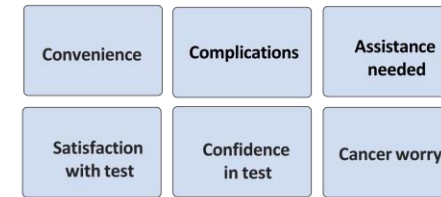
Results



Available instruments on CRC patient perceptions concentrate on predictors of screening compliance rather than actual testing experiences



Interviews with N=14 English and Spanish speaking patients and N=9 primary care physicians revealed **6 important domains**:



We modified 8 existing survey items and developed 10 new items



After cognitive interview with N=10 English speaking older adults, dropped one item and incorporated open-ended responses for some questions



Then translated into Spanish for further cognitive testing with N=5 Spanish speaking older adults and made minor modifications to two survey items and one answer scale

Final instrument has 17 items (see handout)

Conclusions

- Development of this new PRO/PREM instrument specifically for colon polyp surveillance is feasible
- Data collection to psychometrically test instrument is ongoing
- Will provide valuable insights to complement clinical outcomes and support patient-centered decision-making in polyp surveillance

Patient Questionnaire



9. Thinking about your last colon cancer test overall, how convenient was it?

Not at all A little bit Somewhat Quite a bit Very much

10a. Thinking about your last colon cancer test overall (please respond by marking one box per row):

	Not at all	A little bit	Somewhat	Quite a bit	Very much
How much physical discomfort did you feel with your colon cancer test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How hard was it for you to do all the steps to complete your colon cancer test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How self-conscious did you feel with your colon cancer test?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10b. If you would like to tell us more about any of your responses, please do so here:

11a. How much help did you need from another person to do all the things you needed to do to complete your colon cancer test?

None A little Some A lot

11b. If you would like to tell us more, please do so here:

The next questions ask you to think about your feelings in general.

17a. How confident are you that your colon cancer test will find cancer early if you have it?

- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Not at all
confident | A little
confident | Somewhat
confident | Very
confident | Extremely
confident |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

17b. If you would like to tell us more, please do so here:

18. What do you think your chances are of having a complication while doing your colon cancer testing?

- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| None at all | Low | Medium | High | Very high |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

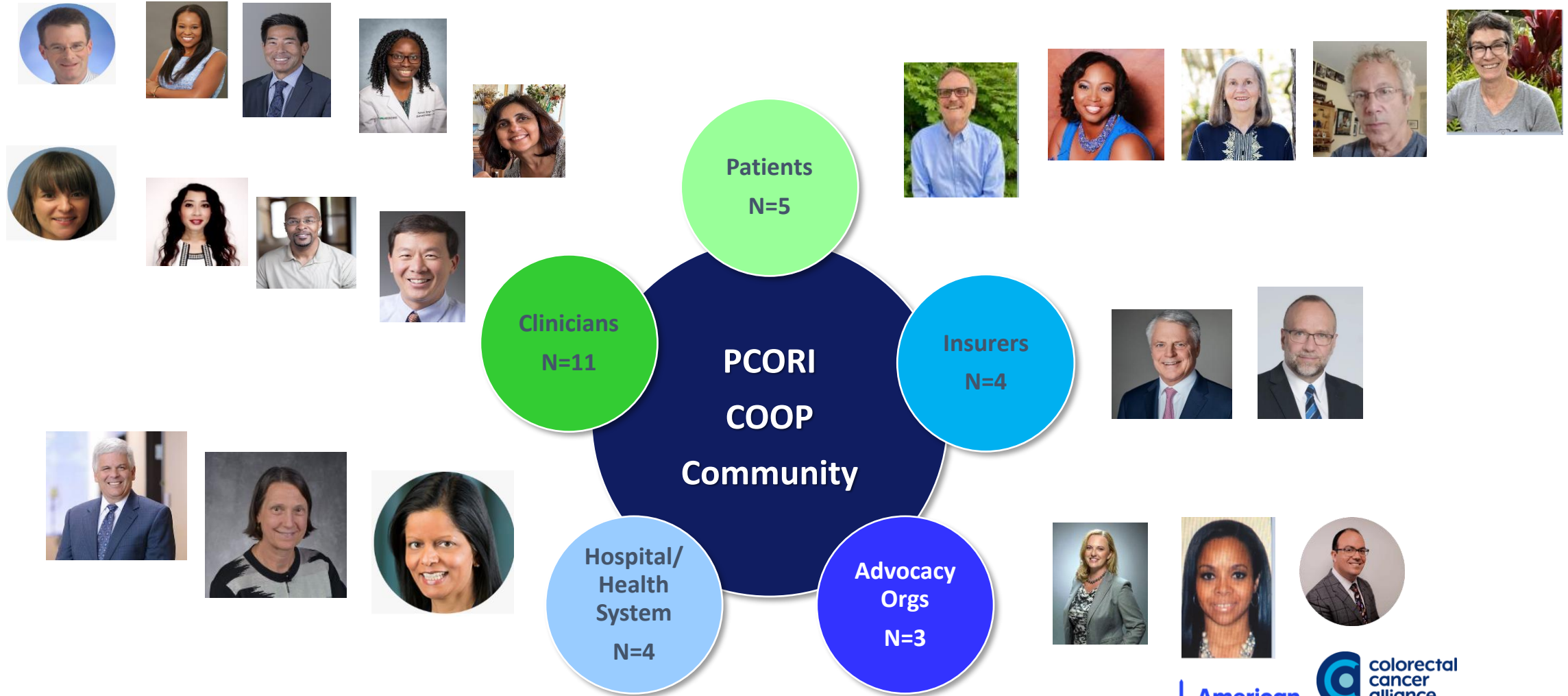
19. What do you think your chances are of getting colon cancer?

- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Very low | Low | Medium | High | Very high |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

20. Overall, how worried are you that you might get colon cancer someday?

- | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|
| Not
worried | Somewhat
worried | Worried | Very
Worried |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

COOP Stakeholder Advisory Panel



The COOP Trial

- Large multicenter trial aiming to enroll nearly 9000 participants
- First in the US to evaluate FIT as a surveillance option following low risk polyps
- Will recruit from a diverse group of sites: academic health systems, VA medical centers, large single specialty GI group, and large integrated multispecialty medical group