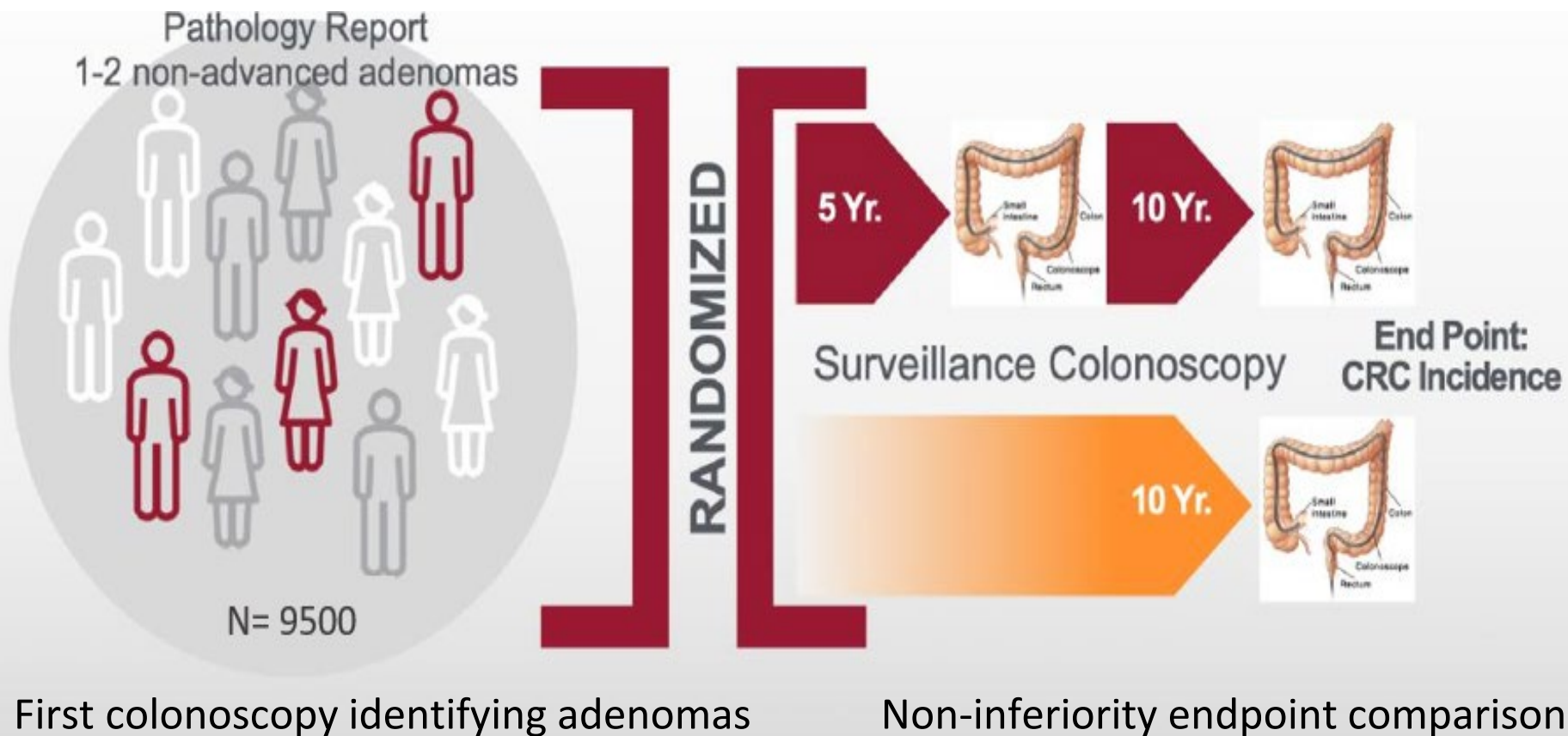


FORTE: Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomas



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Pittsburgh, PA

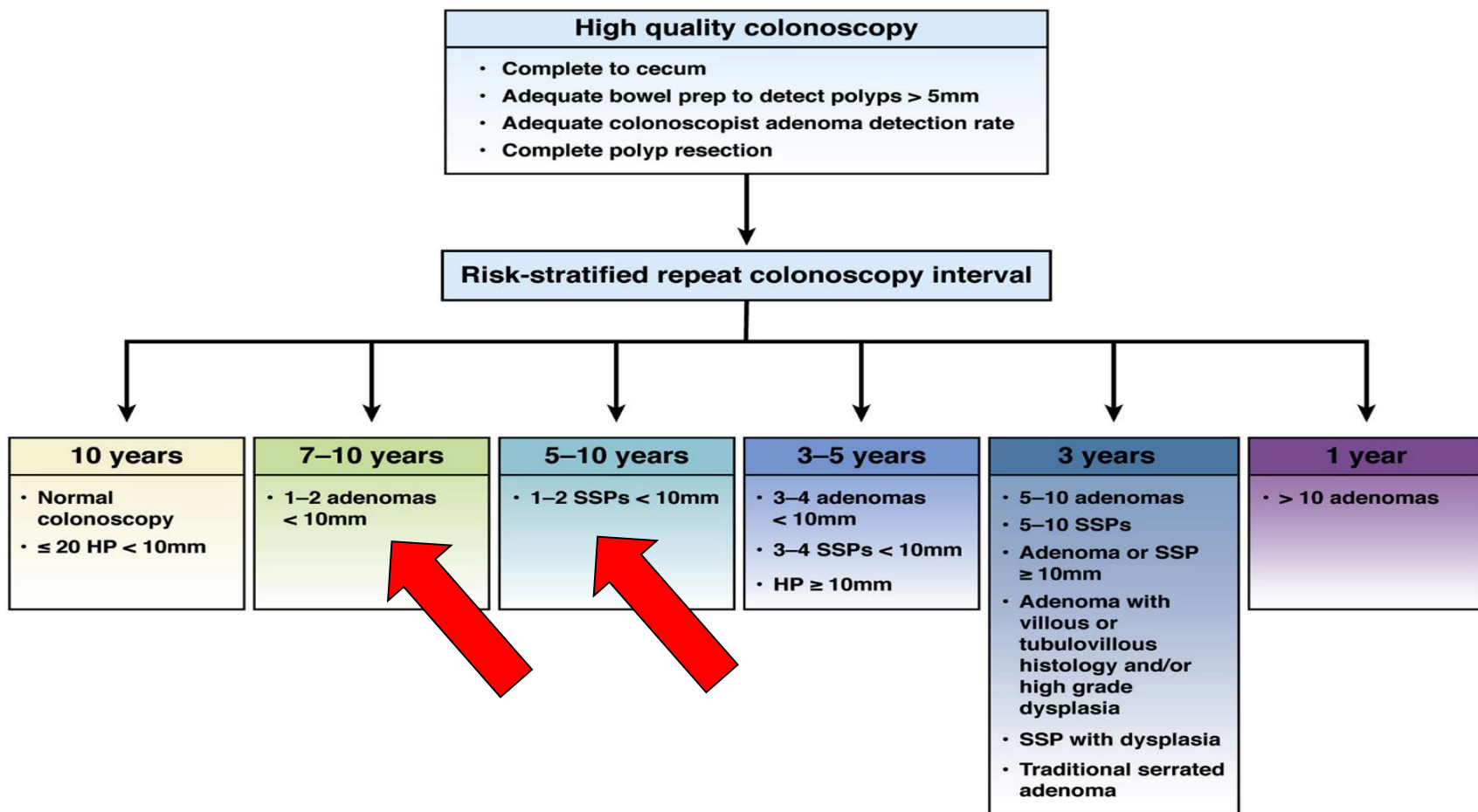
Schema



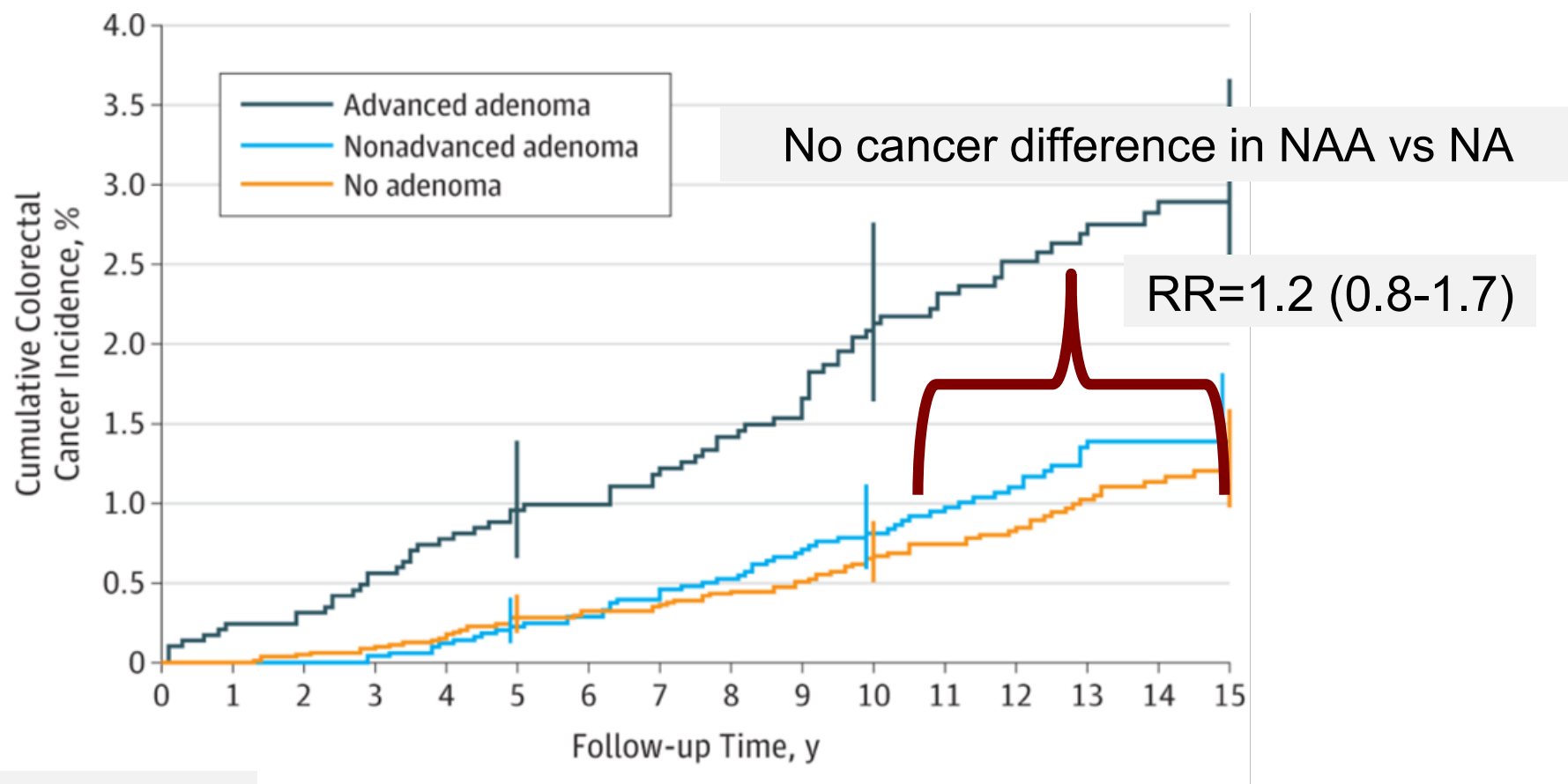
MSTF Surveillance Recommendations: 2012

No polyps, or hyperplastic polyps in rectum/sigmoid		
Repeat in 10 years		
Neoplasia found		
Serrated polyps/lesions	High risk adenomas	Low risk adenomas
Serrated polyposis Repeat in 1 year	> 10 Adenomas Repeat in less than 3 years	1–2 Tubular adenomas < 10 mm Repeat in 5–10 years
≥ 10 mm or With dysplasia or traditional serrated adenoma Repeat in 3 years	3–10 Adenomas Repeat in 3 years	
< 10 mm in Proximal colon and without dysplasia Repeat in 5 years	Villous adenoma(s) or tubular adenoma(s) ≥ 10 mm Repeat in 3 years	
	Adenoma(s) with high grade dysplasia Repeat in 3 years	

These recommended intervals assume a complete exam to cecum, adequate bowel prep, and complete removal of polyps at the baseline exam.



PLCO: Long-term CRC Incidence



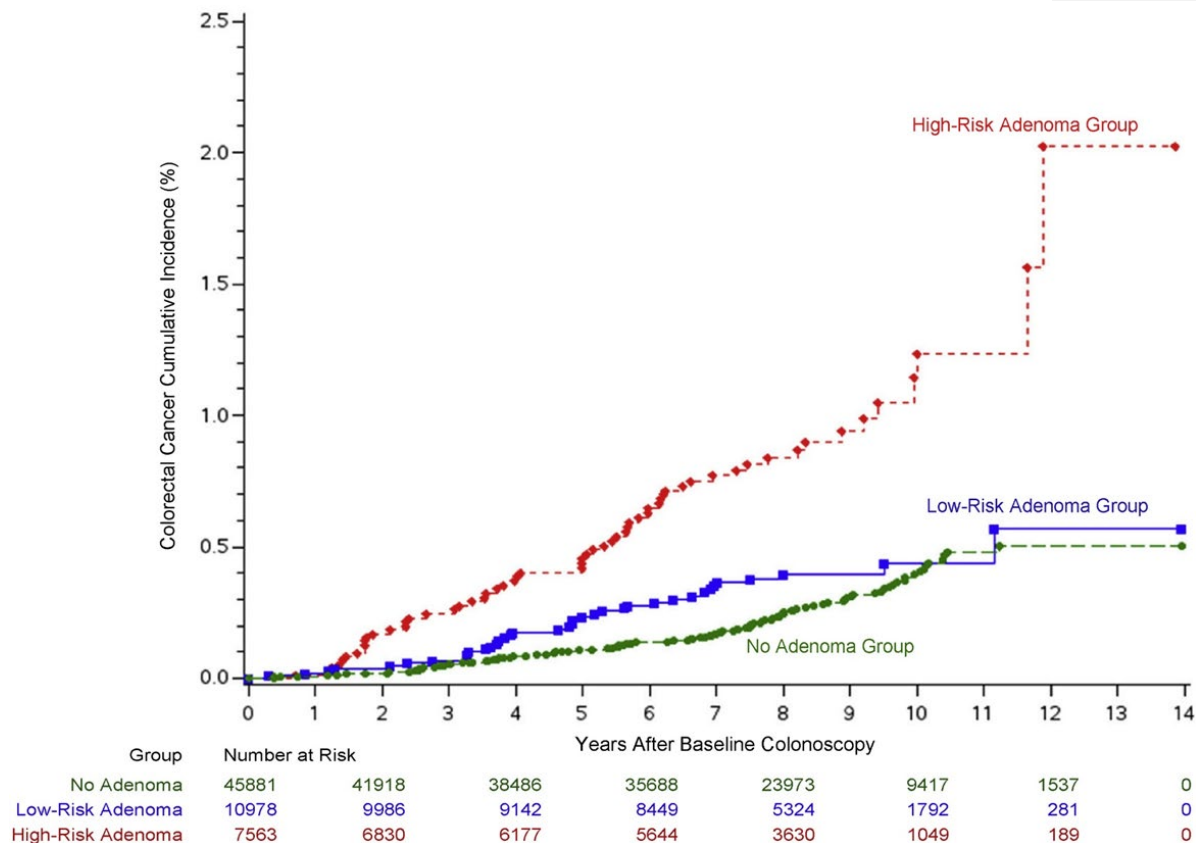
N= 16,000

Click. JAMA 2018;319:2021

CRC Risk after Adenoma: Kaiser

Cumulative Cancer Risk at 14 years

Lee. Gastro 2020; 158:884



If the cancer risk is similar at 10 years,
why bring people back for surveillance
colonoscopy at 5 years?

Problem: Fly in the Ointment

Ignoring surveillance colonoscopy and adenoma removal that already occurred!



Surveillance Utilization

	No Adenoma	Non Adv Adenoma	Advanced Adenoma
YEAR 6	9.2	40.5	60.0
YEAR 10	19.8	58.8	72.7

Advanced Adenoma FOUND/REMOVED

YEAR 6	1.7	4.0	10.5
YEAR 10	3.9	6.4	13.3

Not accounting for the potential benefit of surveillance colonoscopy

- Higher rate of surveillance/adenoma removal in subjects with non-advanced adenoma may have reduced CRC incidence in that group
- Without the extra surveillance/adenoma removal, non-advanced adenoma may have a higher rate of CRC than the no adenoma group

Administrative Structure

liveForte
A COLORECTAL CANCER PREVENTION TRIAL

FORTE



NCORP

NCI

**Community Oncology
Research Program**

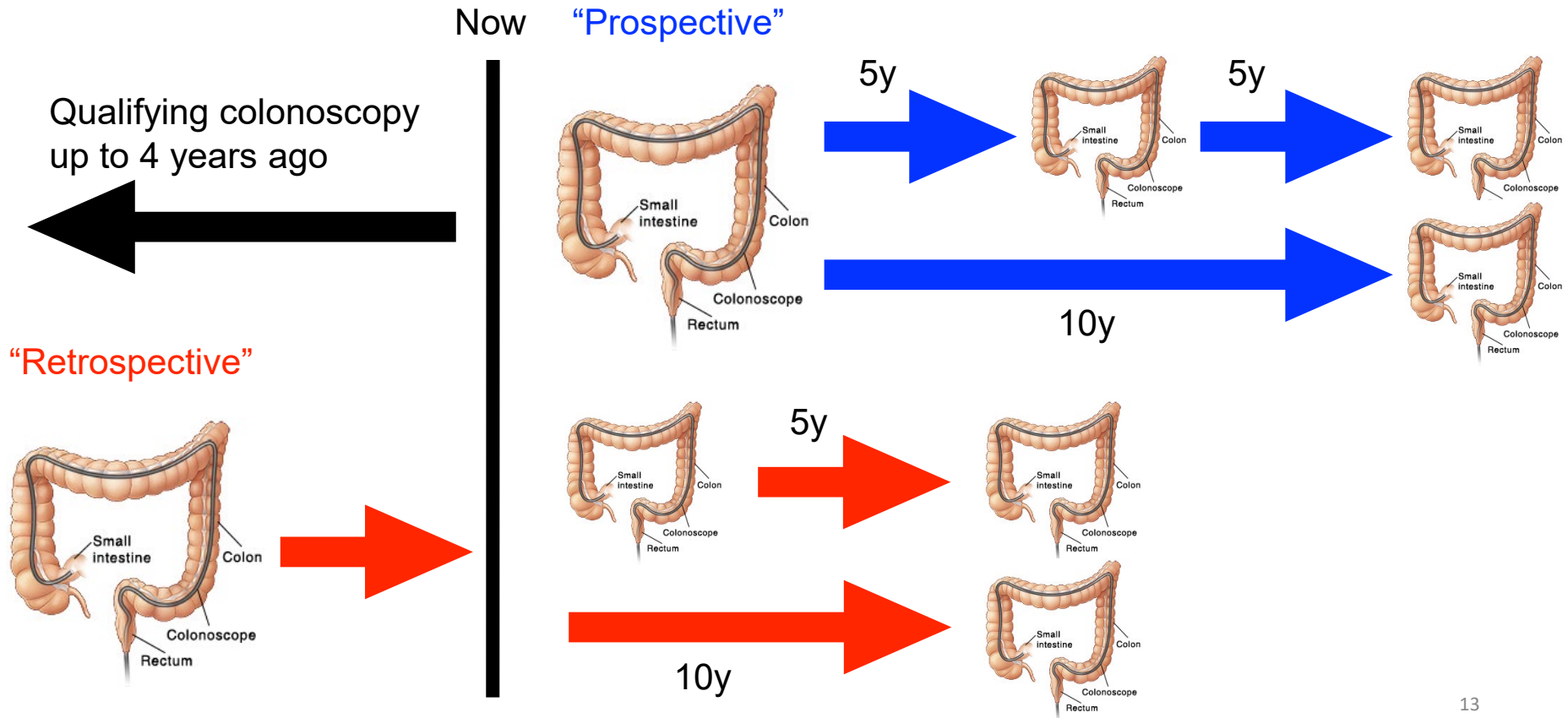
A program of the National Cancer Institute
of the National Institutes of Health

NRG
ONCOLOGY

Advancing Research. Improving Lives.™

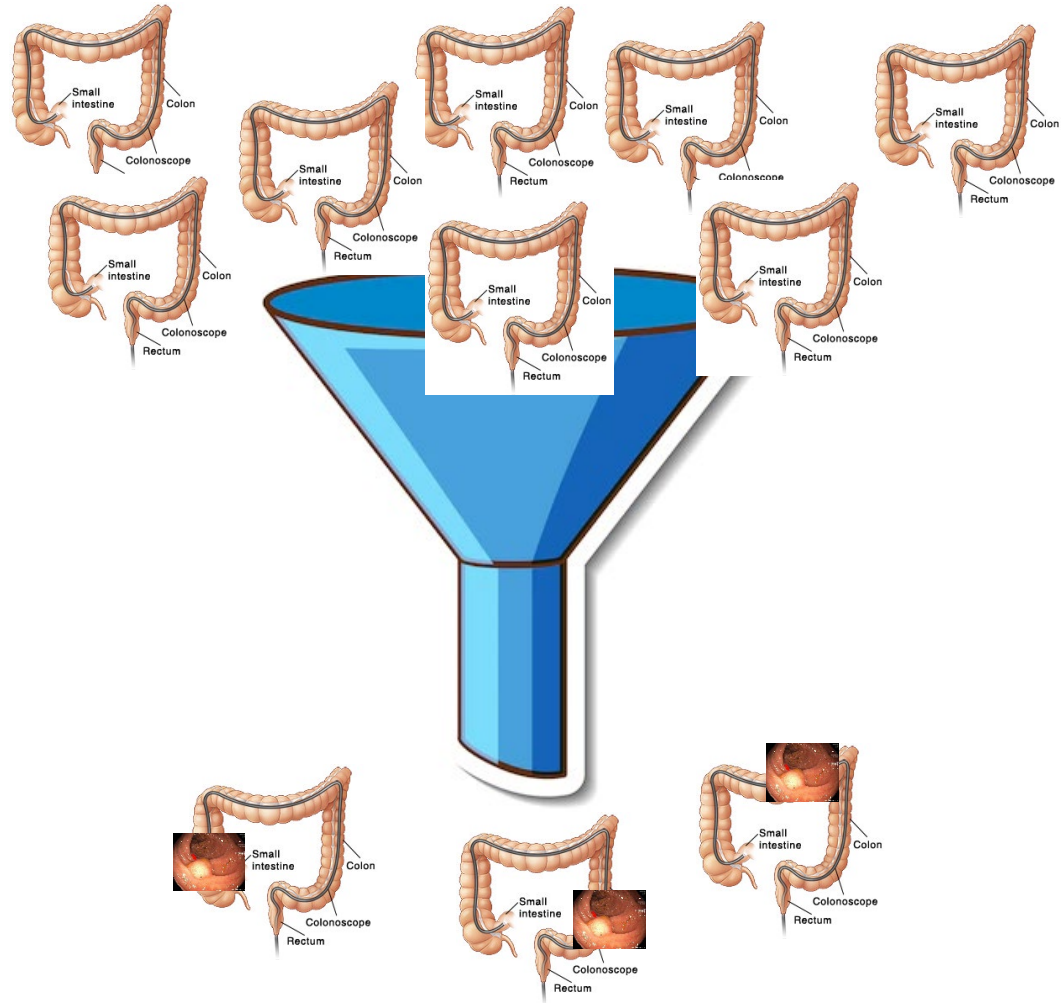
- Site reimbursement is adequate to support trial
- Network start up payment – 5K
- Volume Incentives – more is more
- Participant Allowance ~ \$40.00
- Minimal Patient burden: few questionnaires, blood/stool collection – 15 min in-person appt
- Yearly follow up can be remote
- Home blood draw/e-consent
- Slew of recruitment materials developed
- Natural Language Processing services

“Retrospective” Recruitment



Eligible: 1-2 Non-advanced adenomas up to 4 years ago

- If you have access to a database of colonoscopy exams and associated pathology reports -
Natural Language Processing (NLP) provider:
Pieces
- Can work with IT at sites, facilitate analysis of prior reports to identify potentially eligible subjects for contact. No cost to site.



NCORP
NRG

GI Practices + VA



Success

Recruitment – as of 5/2/23

FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps)

Protocol Status: **ACTIVE**

Protocol Status Date: 06-Oct-2021

Activation Date: 06-Oct-2021

Lead Organization: NRG

NCI Program: NCORP

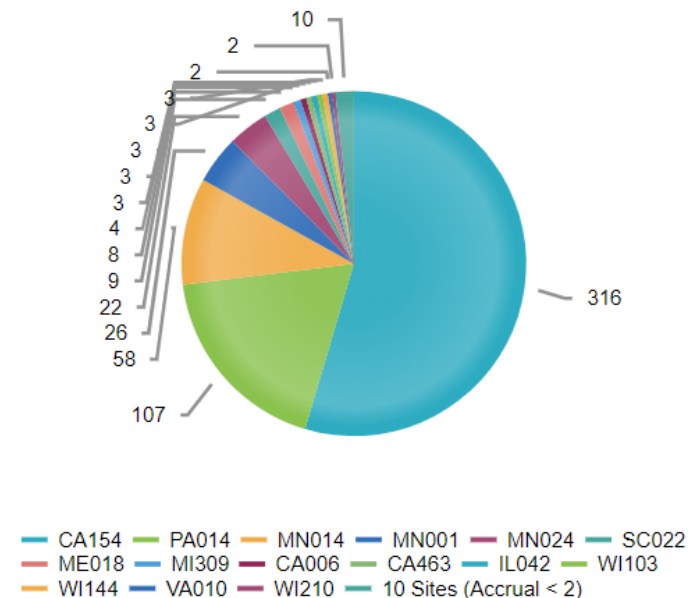
Phase: III

Country Participation: 

Patient Accrual: As of 02-May-2023 08:30:11 AM

Step Type	Step(s)	Planned	Actual
Intervention	1	9500	579

Patient Intervention Accrual by site



84 in month of 3/23

Centers Enrolling

#	Site	Site Name	Site Initial Approval Date	Intervention Accrual Total	Date Of First Intervention Accrual	Date Of Last Intervention Accrual ▾
1	PA014	UPMC-Presbyterian Hospital	06-Dec-2021	107	21-Feb-2022	01-May-2023
2	CA154	Kaiser Permanente-Vallejo	11-Nov-2021	316	10-May-2022	28-Apr-2023
3	MN001	Regions Hospital	08-Oct-2021	26	06-Oct-2022	28-Apr-2023
4	MN024	Essentia Health Cancer Center	08-Nov-2021	22	24-Aug-2022	28-Apr-2023
5	IL042	John H Stroger Jr Hospital of Cook County	22-Mar-2022	3	28-Mar-2023	24-Apr-2023
6	MN127	Essentia Health Virginia Clinic	08-Nov-2021	1	24-Apr-2023	24-Apr-2023
7	CA006	UCLA / Jonsson Comprehensive Cancer Center	27-Jan-2022	3	14-Feb-2023	11-Apr-2023
8	IL043	Rush University Medical Center	24-Jan-2022	1	11-Apr-2023	11-Apr-2023
9	CA760	Kaiser Permanente-San Marcos	02-May-2022	1	04-Apr-2023	04-Apr-2023
10	PR046	Centro Comprensivo de Cancer de UPR	12-Aug-2022	1	04-Apr-2023	04-Apr-2023
11	VA010	Virginia Commonwealth University/Massey Cancer Center	17-Oct-2022	2	07-Mar-2023	04-Apr-2023
12	WI031	Marshfield Medical Center-Marshfield	28-Jan-2022	1	29-Mar-2023	29-Mar-2023
13	MI309	Spectrum Health Reed City Hospital	29-Dec-2021	4	06-Apr-2022	23-Mar-2023
14	MN012	Essentia Health Saint Joseph's Medical Center	08-Nov-2021	1	21-Mar-2023	21-Mar-2023
15	WI009	Marshfield Medical Center - Minocqua	28-Jan-2022	1	17-Mar-2023	17-Mar-2023
16	WI210	Marshfield Medical Center-River Region at Stevens Point	28-Jan-2022	2	03-Feb-2023	15-Mar-2023
17	ME018	Maine Medical Center- Scarborough Campus	18-May-2022	8	26-Oct-2022	14-Mar-2023
18	WI004	Zablocki Veterans Administration Medical Center	15-Nov-2022	1	27-Feb-2023	27-Feb-2023
19	MN014	Park Nicollet Clinic - Saint Louis Park	08-Oct-2021	58	09-Feb-2022	22-Feb-2023
20	SC022	Ralph H Johnson VA Medical Center	05-Dec-2021	9	09-Aug-2022	10-Feb-2023
21	WI103	Marshfield Clinic-Wausau Center	22-Dec-2022	3	09-Jan-2023	06-Feb-2023
22	CA463	Contra Costa Regional Medical Center	23-Nov-2021	3	05-Aug-2022	17-Jan-2023
23	WI144	Marshfield Medical Center - Weston	28-Jan-2022	3	06-Dec-2022	11-Jan-2023
24	NJ028	Morristown Medical Center	01-Feb-2022	1	11-Nov-2022	11-Nov-2022
25	ND007	Sanford Bismarck Medical Center	10-Jan-2022	1	31-Aug-2022	31-Aug-2022

Current Recruitment

Race/Ethnicity Group	Current (n=502) %	Expected (n=9500) %
Race		
American Indian or Alaska Native	0.2	0.3
Asian	7.4	3.1
Black or African American	8.2	8.3
Native Hawaiian or other Pacific Islander	0.8	0.2
White	74.3	88.1
Multiracial	1.4	0.0
Not reported/Unknown	7.8	0.0
Ethnicity		
Hispanic or Latino	9.4	4.7
Not Hispanic or Latino	67.9	95.3
Not reported/Unknown	22.7	0.0

US Population:

Asian: 5.7%

Black or African
American: 14.2%

Hispanic: 18.9%

- Blood and stool collection for future study
 - Blood at enrollment
 - Stool at enrollment, year 2, year 4 - with dietary inventory
- Collecting validated patient reported outcomes - PROs
- Yearly incidence of common health conditions

- Need more sites!
- Opportunity to participate in landmark trial
- Reimbursement will cover your costs
- Consider getting on board!

FORTE: 3-1 Favorite Kentucky Derby 2023



FORTE Team

FORTE
live **en**
A COLORECTAL CANCER PREVENTION TRIAL

Robert E. Schoen – PI/Protocol chair
Jeffrey Dueker – Protocol co-chair
Douglas Corley – Chief scientific officer
Hannah Bandos – Lead Statistician
Jinbing Bai - Microbiome

NCORP PI's

Deborah Bruner
Joan Walker
Lisa Kachnic

Cancer Prevention Committee

Warner Huh
Julie Bauman

NCI

Sandra Russo
Worta McCaskill-Stevens

NRG

Cheryl Leow
Kristen Kotsko
Martha Duncan
Julie Kardell
Judy Langer
Francy Fonzi

