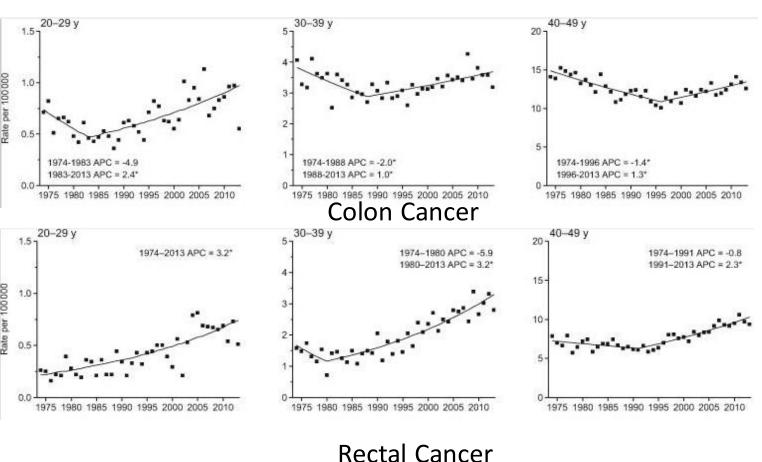


### **Background:**

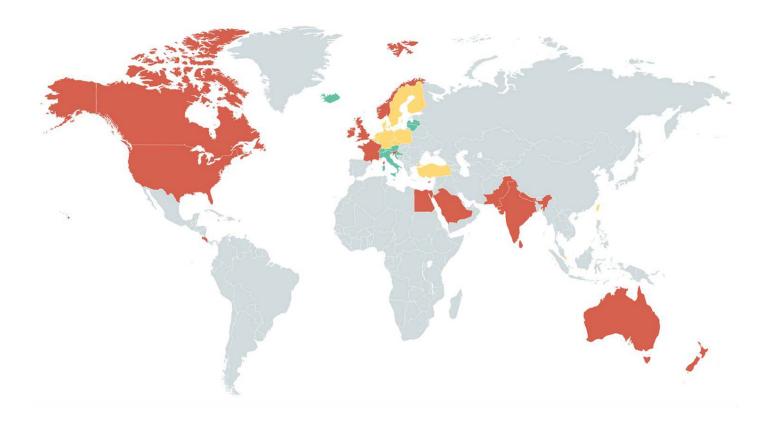
The incidence of colorectal cancer (CRC) in people under 50 years old is increasing without a

clear established cause

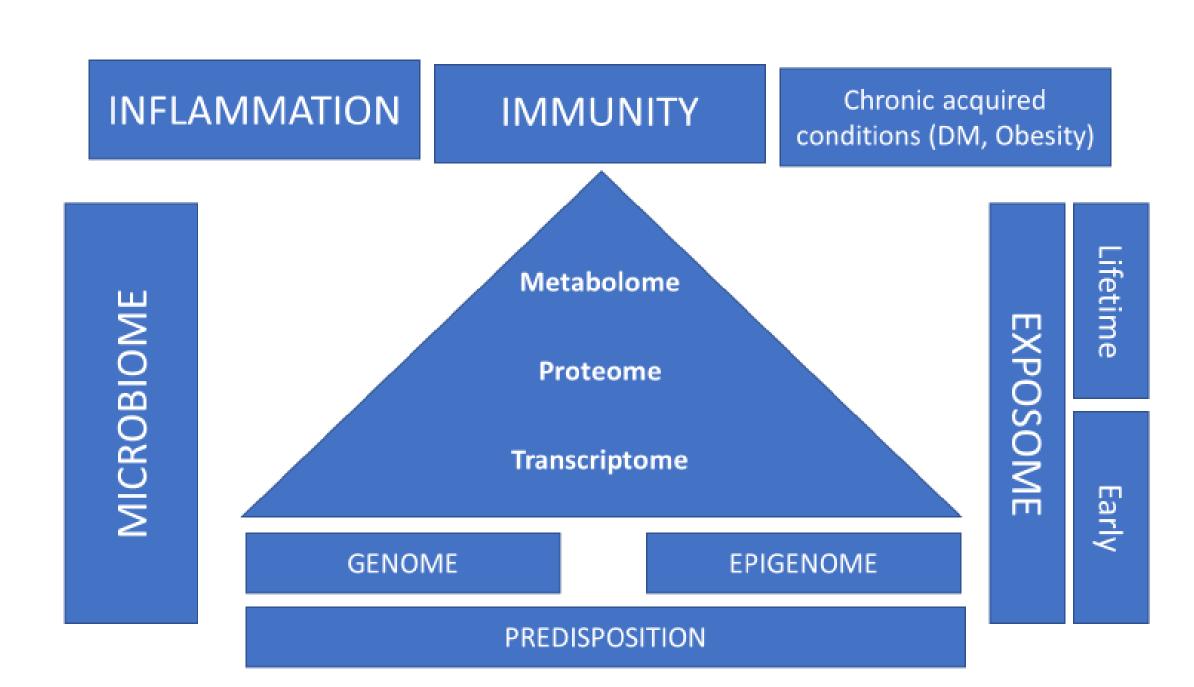


Ages 20-49 years New Zealand United Kingdom Canada USA, SEER (9 registries Switzerland (6 registries France (9 registries Brazil, Goiania Philippines, Manila Korea (5 registries) India, Chennai Thailand (4 registries) Turkey (2 registries) Netherlands Norway Costa Rica Finland Slovakia Estonia Japan (4 registries) Bulgaria Spain (9 registries) Poland, Kielce Lithuania Siegel et al, GUT 2019

# **EOCRC.** Increasing incidence.



- Group 1 High increase of the incidence
- Group 2 Moderate increase of the incidence
- Group 3 Decrease or manteinance of the incidence



### **Fight Colorectal Cancer** Early Age Onset (EAO) Working Meeting

February 1, 2019 Denver, Colorado

Leads: Andrea (Andi) Dwyer Reese Garcia Sharyn Worrall, Anjee Davis









Prof. Rogelio González Sarmiento

Instituto de Investigación Biomédica de Salamanca (IBSAL) e Instituto de Biología Molecular y Celular del Cáncer (IBMCC), Salamanca

Dr. Miguel Urioste Azcorra Centro Nacional de Investigaciones Oncológicas (CNIO), Madrid

#### Venue:

Hospital Universitario Fundación Jiménez Díaz

- Aula Magna - Av. de los Reyes Católicos 2, Madrid



In collaboration with:





# F!GHT COLORECTAL CANCER

Early-age Onset Colorectal Cancer Think Tank

Loews Vanderbilt Hotel: 2100 West End Ave., Nashville, TN 37203

### **December 1: Think Tank Meeting**

TIME AND PLACE	TOPIC	
7am-7:45am Blackbird Studio	Breakfast	
7:45am-8am Blackbird Studio	Welcome & Opening Session	
	Speakers	
	* Anjee Davis, MPPA, President, Fight Colorectal Cancer	
	* Cathy Eng, MD, FACP, FASCO, Medical Oncologist; Professor of Medicine, Division on Hematology/Oncology; Co-Leader, VICC Gastrointestinal Cancer Research Program; Co-Director, GI Oncology, Director, VICC Young Adults Program; Vanderbilt University	
	* Phil Daschner, MSc, Program Director, Division of Cancer Biology, Cancer Immunology, Hematology, and Etiology Branch; National Cancer Institute	
8am-8:30am Blackbird Studio	Early-age Onset (under 50): Path to a Cure	
	Speakers	
	* Andrea (Andi) Dwyer, BS, University of Colorado Cancer Center-Advisor to Fight CRC	
	* Jill MacDonald, EAO Colon Cancer Survivor, Fight CRC Ambassador	
	* Cathy Eng, MD, FACP, FASCO	
8:30am-9am Blackbird Studio	Understanding Health Differences in Early Onset Colorectal Cancer Through Data	
	Speaker	
	<ul> <li>* Andrea Cercek, MD, (virtual) Gastrointestinal Oncologist; Co-Director of the Center for Young Onset Colorectal and Gastrointestinal Cancers; Section Head, Colorectal Cancers; Memorial Sloan Kettering Cancer Center</li> </ul>	
	* Rebecca L. Siegel, MPH, American Cancer Society, Senior Scientific Director Cancer Surveillance Research	

TIME AND PLACE	TOPIC
9am-10:15am Blackbird Studio	State of the State EAO Post Pandemic (US vs. Global Funding)
	Moderator
	* Chris Lieu, MD, Associate Director for Clinical Research, Director of GI Medical Oncology at the University of Colorado Cancer Center, Associate Professor in the Division of Medical Oncology, and Associate Director for Clinical Research at the University of Colorado School o Medicine; Vice-Chair of the National Cancer Institute Colon Cancer Task Force
	Panelists
	International Investment
	* José Perea García, MD, PhD, MSc, Consultant Surgeon; Adjunct Professor of Surgery; Institute of Biomedical Research of Salamanca, Madrid
	NCI Activities and Initiatives on EOCRC Research
	* Phil Daschner, MSc, Program Director; Division of Cancer Biology, Cancer Immunology, Hematology, and Etiology Branch; National Cancer Institute
	<ul> <li>Matt Young, PhD, Program Director for Gastrointestinal Cancers at the Cancer Biomarkers Research Group, Division of Cancer Prevention, National Cancer Institute</li> </ul>
	Cancer Grand Challenge on EAO (International Component)
	* Andrew Kurtz, PhD, (virtual) Program Director of National Cancer Institute's Center for Strategic Scientific Initiatives (CSSI), Co-Leader of Cancer Grand Challenges
	* Anthony Dickherber, PhD, (virtual) Program Director in the National Cancer Institute's Office of the Director, Center for Strategic Scientific Initiatives, and Director of the NCI Innovative Molecular Analysis Technologies
	Department of Defense Funding
	* Julia Huiberts, MS, Program Manager, Peer-Reviewed Cancer Research Program, Defense Health Agency
	NIEHS Presenting
	* Abee Boyles, PhD, (virtual) Health Scientist Administrator, National Institute of Enviornmental Health Sciences
	* Arun Pandiri, PBVSc & AH, MS, PhD, DACVP, DABT, (virtual) Leader, Molecular Pathology Group, Cellular and Molecular Pathology Branch, National Institute of Environmental Health Sciences

10:30am–2:15pm Track 1: Southern Ground A/B Track 2: Blackbird Studio	Track 1: Research Opportunities for Biology and Etiology: Exposures/ Microbiome/Study- Design Cohorts	Track 2: Research Opportunities for Under 50 Risk Stratification and Population-based Early Intervention Strategies
10:30am-10:45am	Introduction	Introduction
	Moderators	Moderators
	* Caitlin Murphy, PhD, MPH, Associate Professor, Health Promotion & Behavioral Sciences; University of Texas Health Houston, School of Public Health  * Cathy Eng, MD, FACP, FASCO, Medical Oncologist; Professor of Medicine, Division on Hematology/ Oncology; Co-Leader, VICC Gastrointestinal Cancer Research Program; Co-Director, GI Oncology, Director, VICC Young Adults Program; Vanderbilt University	* Josh Demb, MPH, PhD, Postdoctoral Fellow at UC San Diego Division of Gastroentorology, Department of Medicine, UC San Diego  * Fola May, MD, PhD, MPhil, Associate Professor of Medicine at the University of California Los Angeles (UCLA), Director of Quality Improvement in the Vatche and Tamar Manoukian Division of Digestive Diseases, Director of the May Laboratory, Associate Director of the UCLA Kaiser Permanente Center for Health Equity
10:45am-11:30am Track 1: Southern Ground A/B Track 2: Blackbird Studio	Environmental & Occupational Exposures Key Considerations for Discussion Exposome  Panelist  * Dean Jones, PhD, (virtual) Professor, Department of Medicine, Pulmonary Division; Professor, Department of Biochemistry; Director of the Emory Clinical Biomarkers Laboratory; Co-Director of the Emory Center for Clinical and Molecular Nutrition; Emory University	Contrasting Colorectal Cancer Screening; Guidelines Worldwide  Panelists  * Ann Zauber, PhD, Attending Biostatistician, Memorial Sloan Kettering Cancer Center  * Iris Lansdorp-Vogelaar, PhD, (virtual) Professor, Department of Public Health of Erasmus MC, Erasmus MC
11:30am-12:15pm Track 1: Southern Ground A/B Track 2: Blackbird Studio	Microbiome or Epigenome and CRC Panelists  * Cynthia Sears, MD, Professor of Medicine and Oncology, Johns Hopkins University School of Medicine; Professor of Molecular Microbiology and Immunology, Bloomberg School of Public Health; Microbiome Program Leader, Bloomberg-Kimmel Institute for Cancer Immunotherapy; Johns Hopkins  * Mariana Byndloss, DVM, PhD, Assistant Professor of Pathology, Microbiology and Immunology; Vanderbilt University	Research in Implementation of Risk and Family History and Risk Stratification  Panelists  * José Perea García, MD, PhD, MSc, Consultant Surgeon; Adjunct Professor of Surgery; Institute of Biomedical Research of Salamanca  * Heather Hampel, MS, CGC, Associate Director, Division of Genetics and Genetic Counseling; Clinical Professor, Department of Medical Oncology and Therapeutics Research; City of Hope National Cancer Center Ohio

12:45pm-1:30pm Track 1: Southern Ground A/B Track 2: Blackbird Studio	Aging Markers and Early-age Onset Colorectal Cancer  Panelist  * Kit Curtius, PhD, Assistant Professor of Medicine, Division of Biomedical Informatics; Associate Member of the Cancer Control Program at UCSD Moores Cancer Center, UC San Diego	Populating Identification Using Stool-based Screening and Emerging Technologies (Triage Symptoms and Beyond) and Research Opportunities for EAO and Beyond (FIT, rRNA, MCEDs)  Panelist  * Aasma Shaukat, MD, MPH, Robert M. and Mary H. Glickman Professor of Medicine, Dept. of Medicine at NYU Grossman School of Medicine; Professor, Dept. of Population Health at NYU Grossman School of Medicine; Director, Outcomes Research, Division of Gastroenterology and Hepatology; Co-director, Translational Research Education and Careers; New York University Langone Health
1:30pm- 2:15pm Track 1: Southern Ground A/B Track 2: Blackbird Studio	Track 1 Discussion	Track 2 Discussion

### F!GHT COLORECTAL CANCER®

# TOA CURE REPORT



# PATH TO A CURE REPORT

The four sections of this report provide progress indicators, key messages, opportunities and challenges, and the voice of survivors.

Each indicator has a plan of action to ensure that all champions know how they can play a role in contributing to a path to a cure by:

- \* Creating awareness by helping identify preventable and unpreventable causes of colorectal cancer;
- \* Promoting the importance of screening so colorectal cancer is found early when it is most treatable with less invasive methods, while also advising people to be screened if showing signs and symptoms;
- \* Supporting ongoing research and advancements in innovative treatment options; and
- \* Addressing quality of life beyond diagnosis, treatment, and surgery.

# PATH TO A CURE REPORT

1

### **BIOLOGY AND ETIOLOGY**

**PROGRESS INDICATOR** 

Applying What We Know from Biology and Hereditary Risk to Reduce Late-Stage Colorectal Cancer







# PREVENTION AND EARLY DETECTION

**PROGRESS INDICATOR** 

Advancing colorectal cancer prevention and early detection.



### **TREATMENT**

**PROGRESS INDICATOR** 

Expanding Treatment
Strategies for Colorectal
Cancer Patients, which
have not progressed
quickly enough over time.



### SURVIVORSHIP AND RECURRENCE

### **PROGRESS INDICATOR**

Address quality of life issues and preventive steps to avoid recurrence.



### BIOLOGY AND ETIOLOGY

### **OBJECTIVE 1**

Further research the nature, biology, and implications of CRC throughout the continuum of age

### **OBJECTIVE 2**

Research the role and impact of health disparities in those developing colorectal cancer

### **OBJECTIVE 3**

Improve dissemination and implementation of evidence-based and population-based strategies for genetic and hereditary cancer

### **OBJECTIVE 4**

Progress research and exploratory science to advance our knowledge of Lynch syndrome

### PREVENTION AND EARLY DETECTION

#### **OBJECTIVE 1**

Improve dissemination and implementation of evidence-based CRC screening interventions for the average-risk population

### **OBJECTIVE 2**

Improve dissemination and implementation of evidence-based CRC screening for the increased, high-risk, and symptomatic patients

### **OBJECTIVE 3**

Further research of CRC screening uptake for those younger than 50 to reduce EAO CRC

### **OBJECTIVE 4**

Research in minimally invasive strategies for preventive cancer

### TREATMENT

### **OBJECTIVE 1**

Increase clinical trial enrollment, particularly for late-stage disease, MSS, and EAO patients

### **OBJECTIVE 2**

Increase biomarker and molecular testing (localized vs. metastatic)

### **OBJECTIVE 3**

Design trials that are individualizedsequence therapies

### **OBJECTIVE 4**

Strengthen infrastructure design and development to advance treatment and clinical care

### **OBJECTIVE 5**

Increase federal funding for CRC research to achieve above

### SURVIVORSHIP AND RECURRENCE

### **OBJECTIVE 1**

Develop/research survivorship care delivery intervention and approaches which take into account the whole person

### **OBJECTIVE 2**

Increase the capacity of health care delivery systems, primary care, public health, and health workforce to bridge needs of CRC patients post treatment

### **OBJECTIVE 3**

Expand research efforts to improve and advance development of emerging and new technologies for early detection, screening and prevention of recurrence

# **Everyone has a role to play.**

**Establish Criteria for** Host an **Progress Indicators and Set Priorities Annual Dialogue Measure Each Update Stakeholders and Select Policy-Level Put Pressure on Provide Outcome Reporting Interventions Implementation** 

# **Big Wins for Early Age Onset**

# Section 1: Biology and Etiology

OBJECTIVE 1 Further research the nature, biology, and implications of colorectal cancer, throughout the continuum of age (while also considering younger adults versus older adults). Understanding parameters, including stage, location, histopathology, and underlying genetic and molecular "drivers."

- NCI Launched Funding Opportunity Notice of Special Interest (NOSI): Research on the Etiology, Early Detection, Screening and Prevention of Early-Onset Colorectal Cancer.
- NOT-CA-23-018: NOTICE OF SPECIAL INTEREST (NOSI): RESEARCH ON THE ETIOLOGY, EARLY DETECTION, SCREENING AND PREVENTION OF EARLY-ONSET COLORECTAL CANCER (NIH.GOV)

# Continued: Biology and Etiology

• Fight Colorectal Cancer hosting Early Age Onset Research meeting Dec 1 2023 in collaboration with National Cancer Institute and Vanderbilt University. Global Think Tank planned for June of 2024.

• Fight Colorectal Cancer Early Age Onset Work Group Completed review of red flag signs and symptoms and delays in diagnosis for early onset colorectal cancer. Manuscript submitted for publication the winter of 2023.

# Section 2: Prevention and Early Detection

OBJECTIVE 3 Further research and examination of colorectal cancer screening uptake for those younger than age 50 to reduce early-age onset colorectal cancer.

- •Policy updates: Fight CRC is working with our partners to advance the Access to Genetic Counseling Services Act by increasing congressional support for the legislation.
- •As part of Fight CRC's continued effort to promote colorectal cancer screening beginning at age 45 for those at average risk, we brought together over 50 organizations to push back against guidance from the American College of Physicians calling for screening to begin at age 50.

# Section 3: Treatment

Progress indicator: Expanding treatment strategies for colorectal cancer patients.

•Partnership with Tempus Health and Fight CRC establishing an opensource cohort of highly profiled and standardized patient tumors (information) with clinical outcomes to accelerate research in metastatic CRC.

# TIME TO GET SHIT DONE

For more information or to join us as a champion, contact <a href="mailto:pathtoacure@fightcrc.org">pathtoacure@fightcrc.org</a>

# **EAO Patient Experience Poll**

October, 2023 through a convenience sample approach to understand the unique experiences associated with early age onset colorectal cancer. Shared across various social media platforms such as Twitter, Instagram, Facebook (both general and private advocate pages), Fight CRC social channels and LinkedIn, the poll engaged a broad audience. In addition to the public outreach, targeted emails were sent to encourage participation from members of Colon Club and ColonTown. There were was an impressive response rate with

900 survey respondents. Respondents were patients and caregivers.

Did you experience gaslighting in your colorectal cancer diagnosis?

My sister was gaslit by doctors for months. She was pregnant, and everything was blamed on that. Sadly, it was too late by the time she was diagnosed. She was 36. "



- Did you have insurance issues with treatment and follow-up care?
- Even though my mother died from colon cancer, I have a genetic predisposition, and I had a pre-malignant polyp removed, I have to battle every two years for coverage. "



of EAO patients who responded experienced insurance issues.

- Have you experienced the myth that CRC is an older person's disease?
- Yes, thankfully, though my doctor ordered colonoscopy because of symptoms, not age. The GI was still processing his shock of a 35-year-old with no family history having colorectal cancer when he told me."



of EAO patients who responded experience the CRC age myth

Did your diagnosis impact your education or career plans?

I was diagnosed stage IIIb with one year left of my bachelor's. I had a partial colectomy on Tues. and was submitting an assignment from my hospital bed on Wed. I was cancer free in February and graduated in May."



of EAO patients who responded experienced an impact on education or career plans

- Did you experience changes in body image due to treatments?
- 100% I no longer feel comfortable in my own skin. In the first round, I was sickly skinny. The second time, I gained a ton of weight. I've been cut several times now, and the scars are huge. Not the best for my mental health."



of EAO patients who responded experienced body image issues.

- Did you receive adequate information about the potential long-term effects of treatments?
- Diagnosed at 43, I received little and inaccurate information about long-term chemotherapy side effects. Nearly 12 years later, I experience high blood pressure, glaucoma, hearing loss, and neuropathy in my feet."



of EAO patients who responded face side effects

- Did you experience any career setbacks due to your diagnosis?
- Yes, as a caregiver, I was 'reassigned' due to frequent absences for local chemo, out-of-state medical trips, and constant unplanned caregiving demands, as our state lacked a liver surgeon."



of EAO patients who responded setbacks

Did you receive info about fertility preservation options?

Yes, from my second opinion. He okayed an egg harvest before treatment. I'm grateful I got to do it after losing both my ovaries due to metastatic disease. My first opinion told me I didn't have time; chemo needed to start right away.



of EAO patients who responded received fertility information

Did you face challenges accessing clinical trials or alternative treatment?

Yes, I have limited clinical trials available in Maine and also no options for alternative treatment."



of EAO patients who responded access issues

- Did you face challenges accessing clinical trials or alternative treatment?
- I was presented with a trial option at diagnosis because my NCI hospital was one of the sites for a trial I matched perfectly for."



of EAO patients who responded access issues

Did you face financial strain from treatment and follow-up care?

Yes, couldn't afford to drop to half pay so went back to work too soon and couldn't cope, so lost my job."



of EAO patients who responded from treatment

Did you face financial strain from treatment and follow-up care?





of EAO patients who responded from treatment

Did you face time toxicity related to treatments and follow-up care?

I never heard of time toxicity, just looked it up and that's a big yes."



of EAO patients who responded related to treatment

- Did your diagnosis impact your dating or relationship experiences?
- PP I decided not to date at all during my treatments and battle because it did not feel fair to myself or someone else to take that on with me or to fall in love not knowing how long I would be here."



of EAO patients who responded experienced relationship issues

### **Research Opportunities**

### Under 50 Risk Stratification and Population-based Early Intervention Strategies

- 1. Contrasting Colorectal Cancer Screening Guidelines Worldwide
- 2. Research in Implementation of Risk and Family History in Risk Stratification
- 3. Population Identification using Stool-based Screening and Emerging Technologies

### **Key Questions, Take Aways, and Opportunities**

What do we need to consider when evaluating screening guidelines (domestically and globally)?

How do we develop a systematic way to collect family history?

How do we achieve "80%" in every country, state, and neighborhood?

Where do stool- and blood-based screening methods fit in to screening guidelines?

How do we integrate the microbiome/exposome/etc. to screening and risk stratification strategies?

### **Research Opportunities**

- 1. Infrastructure development registry, biospecimens, EHR access
- 2. International collaboration for research and policy alignment
- Multidisciplinary teams with various stakeholders (industry, advocacy orgs, survivors/caregivers, researchers)

### **Questions/Comments**

- 1. What are the best ways to integrate patients in the research with minimal patient burden
- 2. How do we reconcile the inconsistencies in definitions, data, and processes as we move forward in research (including internationally)?
- 3. Data availability can be a real challenge how do we collaboratively work to ensure sufficient samples for our research, particularly in subgroups?



# **National Cancer Institute & EAO CRC**

# Three new NCI projects on early onset colon cancer funded in 2021 through the Provocative Questions RFA:

- 1. R01CA257971 "UNCOVER: Underlying novel causes of onset of very early cancer" PI: Wan Yang, Columbia University NCI DOC: DCP
- 2. R01CA264217 "Pathogenesis of Early Onset Colorectal Cancer: Microbiome Contributions and Mechanisms" PI: Cynthia Sears, Johns Hopkins University NCI DOC: DCB
- 3. R01CA258169 "A Case-Control Study to Evaluate Broad-Spectrum Antibiotic use and High Birth Weight as Potential Risk Factors for Early-Onset Colorectal Cancer" PI: Chun R. Chao, KAISER FOUNDATION RES. INST. NCI DOC: DCCPS



# National Cancer Institute & EAO CRC

# Notice of Special Interest (NOSI): Research on the Etiology, Early Detection, Screening and Prevention of Early-Onset Colorectal Cancer

The purpose of this Notice of Special Interest (NOSI) is to solicit applications directed toward identifying, characterizing, and mitigating risk factors, identifying biomarkers for early detection, best screening modalities, and preventive interventions for early-onset colorectal cancer (EOCRC), defined as occurring before 50 years of age.



# Fight CRC Advocacy & NCI

# FY23 Labor, Health and Human Services Appropriations Bill – report language

Colorectal Cancer.-The agreement directs NCI to include an update in the fiscal year 2024 Congressional Justification on opportunities to advance progress against colorectal cancer with an emphasis on: (1) opportunities to develop more effective therapeutics; (2) rising rates in people under the age of 50, including rapidly increasing rates in the 20 to 39 year old age range; and (3) the persistent health disparities in prevalence, screening, and outcomes. The update should describe how NCI plans to play a role in addressing these challenges and what existing and future innovative research opportunities can be leveraged to advance progress.



# DoD Peer-Reviewed Cancer Research Program

**Mission**: To successfully promote high-impact research in cancer prevention, detection, treatment, quality of life, and survivorship for Service Members, their families, Veterans, and the American public

**History**: Peer Reviewed Cancer Research Program Established in FY09 with a \$16M appropriation and Congressional language directing 4 topic areas to be funded

- FY09-FY22: \$784.8M, 1,021 awards; FY23 Appropriation \$130M, TBD awards
- o Topics change each year; to date, 34 unique topics have been included
- CRC has been a topic since FY10
- o CRC investment FY10-FY22: \$67.3M, 104 awards



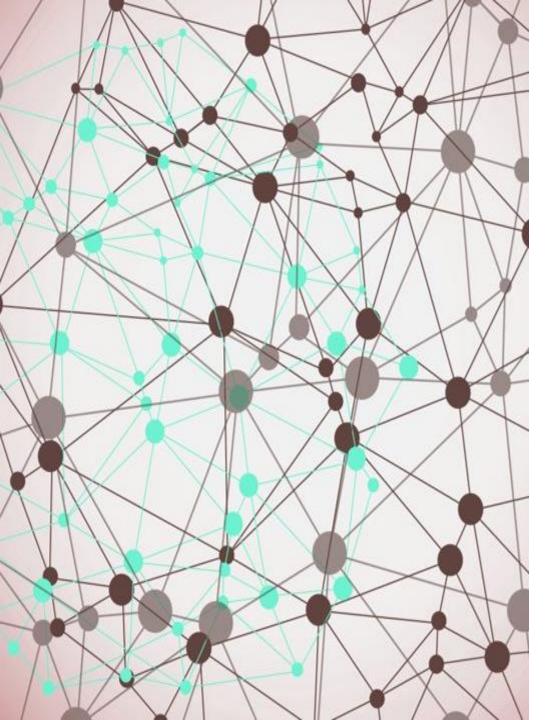
# Fight CRC Advocacy & DoD CDMRP

## The Ask

Provide \$20 Million to Create a
Colorectal Cancer Research
Program within the Department
of Defense (DoD) Congressionally
Directed Medical Research
Program (CDMRP) in the FY24
Department of Defense
Appropriations Bill.

# The Why

- CRC is the second leading cause of cancer death for men and women combined, and the only top 5 cancer killer not to have its own research program within the DoD CDMRP.
- CRC diagnoses are increasing in young people. Those born in 1990 – a key demographic for active duty military – have double the risk of colon cancer and quadruple the risk of rectal cancer as those born in 1950.
- We are leaving good science on the table. In FY21, the DoD received 52 colorectal cancer applications. Of those 21 scored in the outstanding to excellent range, but only 5 projects were funded.



# How Are The Think Tanks Funded

The Path to a Cure Think Tanks are mainly funded by families who truly believe in Fight CRC's Mission and want to help amplify our efforts

3-17 Foundation – Founded by the Insco Family after Michelle Insco passed away from colorectal cancer - was our main donor for the EAO Think Tank

We also have incredible sponsors who help with supporting key elements of the Think Tanks, such as: Wi-Fi, Scholarships for our Research Advocates to attend and the post think tank summary & webinar – Merck, Agenus and SeaGen





# How Fight CRC Supports Research

**Convening Experts** – Bringing healthcare professionals, researchers, patient advocates and other stakeholders together with the goal of knowledge sharing, collaboration, Patient Advocacy, Policy Discussions, Innovation & Technology, and Research opportunities



**Funding Research** – Fight CRC is committed to; Funding research grants and fellows. All grants funded by Fight CRC have supported late-state colorectal cancer. These grants are made possible by donations from our generous donors.



Research Advocates Training and Support (RATS) Program - After completing training, RATS work in partnership with both academic institutions and cancer partners to improve the scientific field by lending their experience and expertise to the research process. RATS have served on various panels; FDA, DOD Peer Reviewed Cancer Research Program, and State Cancer Coalitions.



**Clinical Trail Education** – Understanding the Clinical Trail process is an important aspect of colorectal cancer treatments. We want newly diagnosed individuals to have a better understanding of the right time to explore a clinical trial and how



**Publishing Research** – Huge part of our Patient Education and Research efforts. Fight CRC has published papers on various topics from COVID-19 effects on the CRC community, Precision Medicine, Survivorship, EAO





Apply to become a Research Advocate!

# Getting Involved as an Advocate



Donate to research – 100% of all donations donated to our research fund supports all of our research efforts.



Share our information!