SC11
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9:22am

# Kathryn Lang, M.D., Guardant Health


# The Path to Multi-Cancer Screening

Dr. Kathryn Lang, MD, MRes, MRCP, FRCPath

# About Us

# of employees
750

Headquarters
Redwood City, CA

CEO
Helmy Eltoukhy, PhD

Year Founded
2013

**Guardant Health** is a leading precision oncology company dedicated to helping conquer cancer through our proprietary blood tests, vast data sets, and advanced analytics


To develop affordable multi-cancer assays for early detection and recurrence monitoring

Lung

CRC

Breast

Ovarian

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Memorial Sloan Kettering Cancer Center

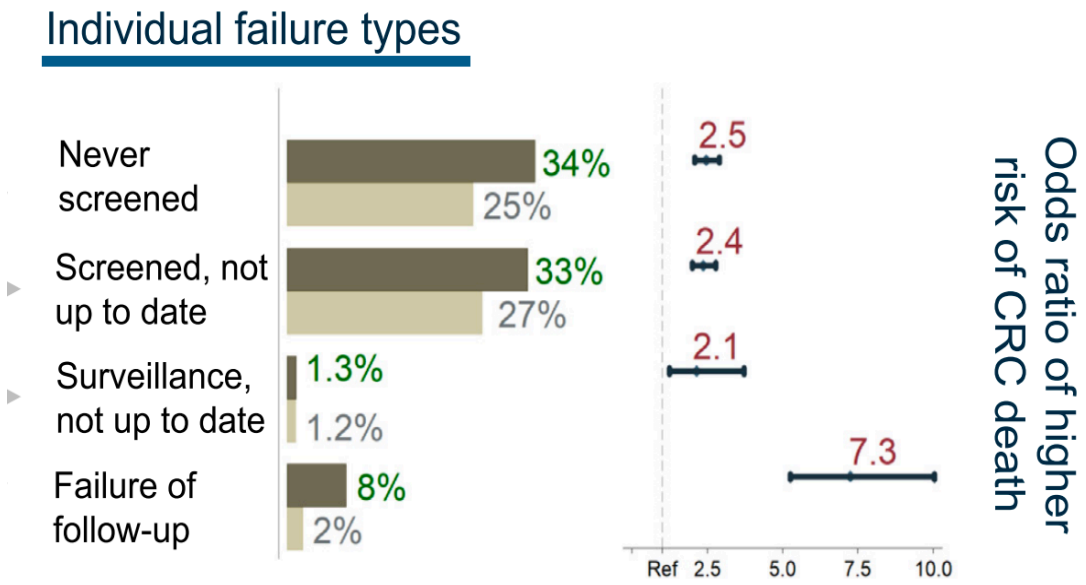
UCSF University of California San Francisco

Wake Forest® Baptist Medical Center

MGH 1811 MASSACHUSETTS GENERAL HOSPITAL

University of Colorado Anschutz Medical Campus

# Why is screening so important in CRC?




- For the unscreened population – the risk of death from CRC was 2.5 times higher than for the screened population
- There remains significant unmet medical need in ensuring that the screen-relevant population remains up-to-date with screening for CRC

Being ‘up-to-date’ with screening reduced CRC death risk by 64%

Doubeni, et al. 2019. Gastroenterology

# GH Timeline to blood-based CRC screening

The development of our CRC screening assay including data readouts and clinical trials


**AACR data presentation**
First data presented on L-2 assay

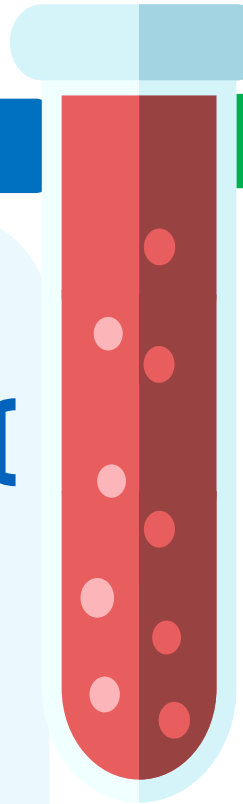
**ECLIPSE study FPI**

**AACR II data presentation**
Further data presented on new cohorts, improved specificity demonstrated

**DDW data presentation**

**ECLIPSE Readout**
Expected 2H 2021

# LUNAR test: Diverse sources of signal motivate multimodal analysis of ctDNA



## Genomic Alterations

ACTACGTACCTG

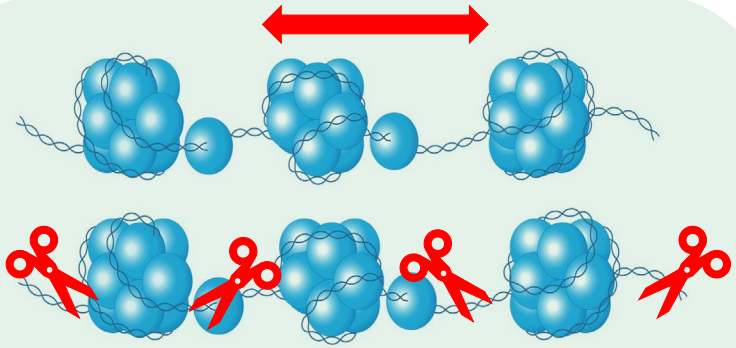
### Genomic Alterations

- SNVs, InDels, Fusions, and CNVs

## Epigenomic Alterations

### Methylation

- Aberrant methylation signals in tumor vs benign tissues



### Nucleosomal Positioning & Fragmentomics

- ctDNA has differential fragment genomic position via nucleosomal positioning or epigenomic alterations at transcription factor binding sites

Kim (Talasaz), 2019. American Association for Cancer Research Annual Meeting. Abstract #916.

# Technical challenges in cancer screening: negative controls

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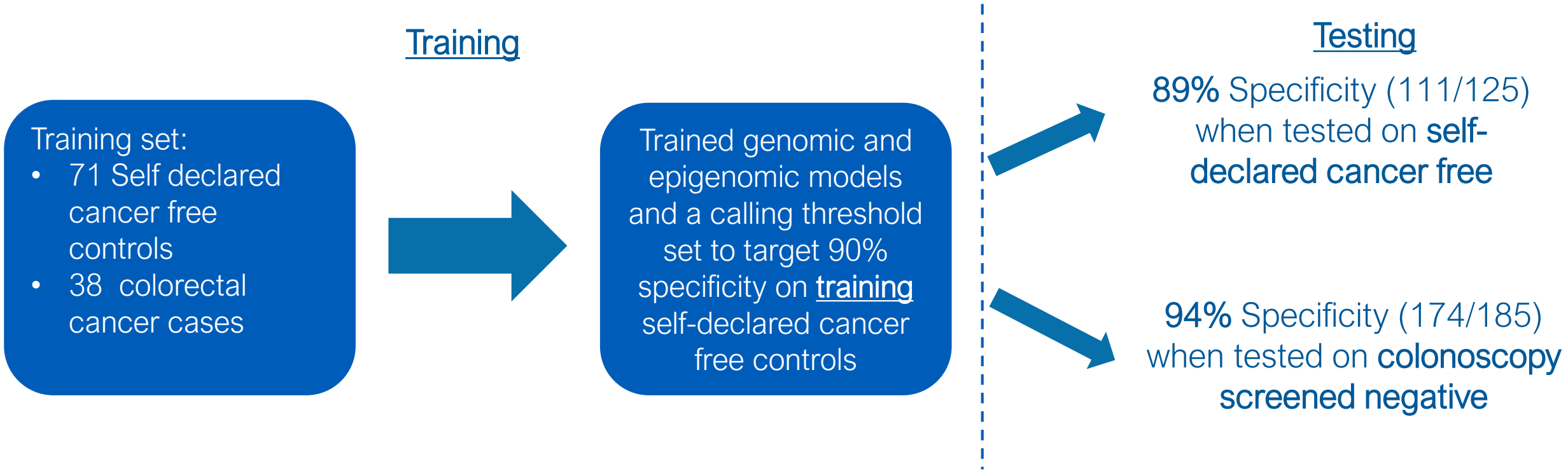
# Specificity Improves from 89% to 94% When Tested on Colonoscopy Screened Negative Controls




Dean (Talasaz), et al. 2020. Digestive Diseases Week 2020. Presentation #Sa1651.

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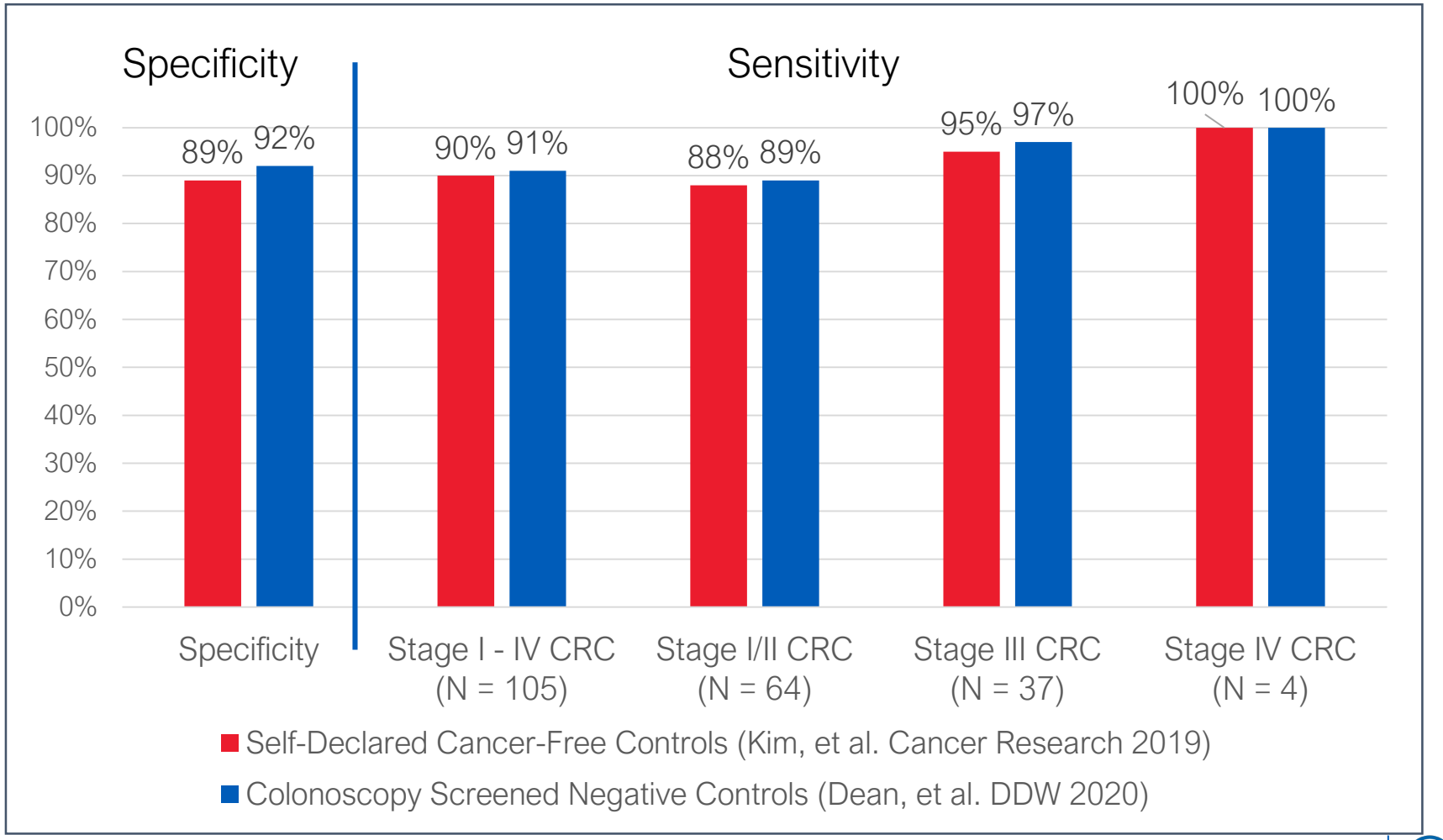
# Colonoscopy-Screened Negative Controls Resulted in Improved Model Performance over Self-Declared Cancer Free Controls




Dean (Talasaz), et al. 2020. Digestive Diseases Week 2020. Presentation #Sa1651.

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# The 4 C's of Colorectal Cancer Screening

## Compliance

- Critical factor in screening
- The most sensitive test is the one that gets done
- Two elements of compliance and two participants
    - Knowledge and completion
    - Doctor and patient

## Capacity

- Aging populations, more screening required
- Colonoscopy capacity is already stretched, moreso by COVID
- Non-invasive options allow for triage to invasive procedure in most developed healthcare economies

## Choice

- Shared decision making is crucial
- Patients are becoming more educated and informed about their choices
- Burdensome testing is viewed negatively

## Cost

- Critical factor
- Cost of test often underestimates true cost of a completed screening event
- Health economic modelling approaches should be critical to guideline committee approvals
- Legislative approaches to reduce out of pocket costs for all screening modalities will be critical

# Key points for developing screening tests

The road is neither easy nor fast, collaboration and novelty is required

01

## Efficacious technology

Innovative technologies in development include NGS, proteomics and others.

02

## Clinical trial execution

Regulatory and evidentiary requirements for screening products are high.  A high bar.

03

## Legislative and payer evolution

The approaches of the past may not serve the solutions of the future and should adapt.

04

## Guideline adoption

Increasing complexity in guideline groups and approaches, standardization considerations.

# 5 minute Q&A

SC Chair/Co-Chair

feed Zoom Q&A to presenter and Track Time

NCI and Production Team

flag Q&A, answer Chat and Slack