



Cancer Diagnostic Devices (CD2) Interagency Task Force

## 2020 CANCER DIAGNOSTICS INNOVATION WORKSHOP ( F O C U S O N N E A R - P A T I E N T U S E )

October 8-9, 2020 | Virtual Meeting via WebEx

Website: <https://events.cancer.gov/cd2/innovation-ws>

### AGENDA

#### DAY 1: October 8, 2020

9:30 am – 10:00 am **Join the Meeting / Computer Check**

10:00 am – 10:15 am **Welcoming Remarks and Meeting Overview/Charge for the Day**

*Douglas R. Lowy, MD, Principal Deputy Director, NCI*

*Christopher Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, NCI*

#### SESSION I: STATE OF THE SCIENCE – CERVICAL CANCER


*Screening for geographically isolated, medically underserved, and otherwise vulnerable communities*

10:15 am – 10:20 am **Session Introduction**

*Chair: Vikrant Sahasrabudhe, MBBS, DrPH, Program Director, Division of Cancer Prevention, NCI*

10:20 am – 10:40 am **Public Health Burden of Cervical Cancer in the U.S.**

*Mona Saraiya, MD, MPH, CAPT, US Public Health Service, Medical Epidemiologist, NCI and CDC*


10:40 am – 10:50 am **Break** 

10:50 am – 11:10 am **Barriers and Facilitators to Patient Care**

*Jacqueline Miller, MD, FACS, CAPT, US Public Health Service, Medical Director, National Breast and Cervical Cancer Early Detection Program, CDC*

11:10 am – 11:30 am **Currently Available Diagnostics**

*Mark Schiffman, MD, MPH, Senior Investigator, Division of Cancer Epidemiology and Genetics, NCI*

11:30 am – 11:40 am **Break** 

11:40 am – 12:00 pm **Community-based Strategies to Improve Cervical Cancer Prevention in Populations  
Experiencing Health Inequities: An Exemplar from Little Haiti**

*Erin Kobetz, PhD, MPH, Associate Director, Population Science and Cancer Disparity, University of Miami*

12:00 pm – 12:20 pm **Considerations from Bench to Bedside to Community**

*Philip Castle, PhD, MPH, Director, Division of Cancer Prevention, NCI*

12:20 pm – 12:30 pm **Q&A**

12:30 pm – 1:30 pm **Lunch Break**

## SESSION II: REMARKS FROM SENIOR LEADERSHIP

1:30 pm – 2:00 pm      *Norman E. Sharpless, MD, Director, NCI*  
*Anand Shah, MD, Deputy Commissioner for Medical and Scientific Affairs, FDA*

## SESSION III: STATE OF THE SCIENCE - BLADDER CANCER


### *Cancer surveillance*

2:00 pm – 2:05 pm      **Session Introduction**  
*Chair: George Netto, MD, Professor and Chair of Pathology, University of Alabama at Birmingham*

2:05 pm – 2:25 pm      **Clinical Course in Bladder Cancer and Clinical Needs for Near-patient Testing**  
*Charles Rosser, MD, MBA, FACS, Medical Director, Cancer Clinical Trials Office, Cedars-Sinai*

2:25 pm – 2:45 pm      **Clinical and Emerging Biomarkers of Bladder Cancer: Monitoring Recurrence**  
*David McConkey, PhD, Director, Johns Hopkins Greenberg Bladder Cancer Institute*

2:45 pm – 3:00 pm      **Q&A**

3:00 pm – 3:10 pm      **Break** 


## SESSION IV: STATE OF THE SCIENCE – LIVER CANCER

### *Screening in high risk patient populations*

3:10 pm – 3:15 pm      **Session Introduction**  
*Chair: Fasiha Kanwal, MD, MSHS, Professor of Medicine, Baylor College of Medicine*

3:15 pm – 3:35 pm      **Current Clinical and Emerging Markers for Liver Disease to Guide Patient Stratification and Risk**  
*Rohit Loomba, MD, Professor of Medicine, University of California San Diego*

3:35 pm – 3:55 pm      **Challenges in Liver Cancer Diagnosis**  
*Xin Wei Wang, PhD, Deputy Chief, Center for Cancer Research, NCI*

3:55 pm – 4:05 pm      **Break** 

4:05 pm – 4:25 pm      **Discovering and Validating Blood-Based Biomarkers for Liver Cancer Early Detection at Point of Care**  
*Shan Wang, PhD, Professor, Stanford University*

4:25 pm – 4:40 pm      **Q&A**

4:40 pm – 4:50 pm      **Wrap-up / Closing Remarks**  
*Robin Vanderpool, DrPH, Branch Chief, Division of Cancer Control and Population Sciences, NCI*

## DAY 2: October 9, 2020

9:30 am – 10:00 am **Join the Meeting / Computer Check**

10:00 am – 10:10 am **Welcoming Remarks and Charge for the Day**  
*Ashim Subedee, PhD, Academic Innovation Lead, Small Business Education and Entrepreneurial Development, NIH OER*  
*Živana Težak, PhD, Associate Director, Center for Devices and Radiological Health, FDA*

### SESSION I: EMERGING FIELD


#### *Liquid biopsy*

10:10 am – 10:15 am **Session Introduction**  
*Chair: Geoff Oxnard, MD, Global Medical Lead, Liquid Franchise, Foundation Medicine*

10:15 am – 10:35 am **Pathways to Bringing Emerging Liquid Biopsy Technologies for Cancer Screening and Near Patient Testing**  
*Nickolas Papadopoulos, PhD, Professor of Oncology, Johns Hopkins University School of Medicine*

10:35 am – 10:55 am **Implementation Needs for Bringing Multi-Cancer Liquid Biopsy Technologies to More Patient Populations**  
*Catherine Marinac, PhD, Member of Faculty, Dana-Farber Cancer Institute*


10:55 am – 11:05 am **Q&A**

11:05 am – 11:15 am **Break** 

### SESSION II: CASE STUDIES

11:15 am – 11:40 am **Overview of the Different Types of Near-Patient Diagnostics, Approvals, and Expectations**  
*Chair: Marina Kondratovich, PhD, Associate Director for Clinical Studies, Center for Devices and Radiological Health, FDA*

11:40 am – 12:00 pm **The OncoE6™ Cervical Test: Updates on the Technology and on Current and Future Avenues of Its Implementation**  
*Johannes Schweizer, PhD, Chief Science Officer, Arbor Vita Corp.*

12:00 pm – 12:10 pm **Break** 

12:10 pm – 12:30 pm **Cologuard Colon Cancer Screening Test (FDA approved)**  
*Graham Lidgard, PhD, Chief Science Officer, Exact Sciences Corporation*

12:30 pm – 12:40 pm **Q&A**

12:40 pm – 1:30 pm **Lunch Break**

### SESSION III: WORLD CAFÉ BREAKOUT GROUPS

1:30 pm – 1:50 pm **Remarks from Senior Leadership**  
*Diana Espinosa, MPP, Deputy Administrator, HRSA*  
*Shari M. Ling, M.D., Deputy Chief Medical Officer, CMS*

**Introduction to the World Café Process**  
*Sonia Rosenfield, PhD, Health Science Administrator, Center for Research Strategy, NCI*

1:50 pm – 2:00 pm **Room Transition / Break** 

2:00 pm – 2:30 pm **World Café Round #1**

2:30 pm – 2:40 pm **Room Transition / Break** 

2:40 pm – 3:00 pm	<b>World Café Round #2</b>
3:00 pm – 3:10 pm	<b>Room Transition / Break</b>  
3:10 pm – 3:30 pm	<b>World Café Round #3</b>
3:30 pm – 3:50 pm	<b>Room Transition / Break</b>  
3:50 pm – 4:25 pm	<b>World Café, Reporting Out</b> <i>Anand Pathak, PhD, MD, MPH, Medical Officer, Center for Devices and Radiological Health, FDA</i> <i>LeeAnn Bailey, PhD, Branch Chief, Center to Reduce Cancer Health Disparities, NCI</i> <i>Sabrina Matoff-Stepp, PhD, Senior Advisor, Office of Planning, Analysis, and Evaluation, HRSA</i>
4:25pm – 4:35 pm	<b>Next Steps and Closing Remarks</b> <i>Henry Rodriguez, PhD, MBA, Director, Office of Cancer Clinical Proteomics Research, NCI</i>

#### World Café Breakout Questions:

- Question #1: Barriers and Challenges Theme - What are major barriers and challenges to bringing cancer diagnostics for near patient use in geographically isolated, medically underserved, and otherwise vulnerable communities?**

Facilitator: Anand Pathak, PhD, MD, MPH, Medical Officer, Center for Devices and Radiological Health, FDA  
Notetakers: Tara Hiltke, PhD, Program Director, Office of Cancer Clinical Proteomics Research, NCI and Camella Rising, PhD, MS, RDN, Cancer Research Training Award Fellow, NCI
- Question #2: Opportunities and Action Items Theme - What are the opportunities (i.e. facilitators, resources) to streamline / accelerate cancer diagnostics from design to implementation in these communities?**

Facilitator: LeeAnn Bailey, PhD, Branch Chief, Center to Reduce Cancer Health Disparities, NCI  
Notetakers: Rao Divi, Program Director, Division of Cancer Control and Population Sciences, NCI and Peter Delnero, PhD, MPH, Cancer Prevention Fellow, NCI
- Question #3: Progress through Collaboration Theme - How can the Federal partners support, incentivize and promote cancer diagnostics developers?**

Facilitator: Sabrina Matoff-Stepp, PhD, Senior Advisor, Office of Planning, Analysis, and Evaluation, HRSA  
Notetakers: Tiffany Gillis-Brown, JD, Public Health Analyst, HRSA and Mark Lowry, PhD, MA, Cancer Research Training Award Fellow, NCI