2020 CANCER DIAGNOSTICS INNOVATION WORKSHOP
(FOCUS ON NEAR-PATIENT USE)

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

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