2020 CANCER DIAGNOSTICS INNOVATION WORKSHOP

Virtual Event, October 08-09, 2020

AGENDA

DAY 1: Thursday, October 8, 2020 (10:00 a.m. – 4:20 p.m.)

10:00 a.m. - 10:30 a.m.	Join the meeting / Computer check
10:30 a.m. - 10:45 a.m.	Welcome, Introduction, and Overview *Christopher Hartshorn, PhD, Division of Cancer Treatment and Diagnosis, NCI* *Henry Rodriguez, PhD, MBA, Office of Cancer Clinical Proteomics Research, NCI* *Sonia Rosenfield, PhD, Center for Research Strategy, NCI* *Ashim Subedee, PhD, Small Business Innovation Research, NCI* *Robin Vanderpool, Dr.P.H., Division of Cancer Control and Population Sciences, NCI* *Živana Težak,PhD, Center for Devices and Radiological Health, FDA* *Sabrina Matoff-Stepp, PhD, Office of Planning, Analysis, and Evaluation, HRSA* *Susan Monarez, PhD, Office of Planning, Analysis and Evaluation, HRSA* *Sarah Harding, Division of Ambulatory Services, CMS*

SESSION I: State of the Science - Cervical Cancer

10:45 a.m. - 10:50 a.m.	Session Introduction *Session Chair: Vikrant Sahasrabuddhe, MBBS, MPH, PhD, Division of Cancer Prevention NCI*
10:50 a.m. - 11:10 a.m.	Public Health Burden of Cervical Cancer and Emerging Trends of its Etiology *Mona Saraiya, MD, MPH, Medical Epidemiologist at NCI and CDC*
11:10 a.m. - 11:20 a.m.	Break
11:20 a.m. - 11:40 a.m.	Barriers and Facilitators to Patient Care *Jacqueline W. Miller, MD, FACS* *CAPT, US Public Health Service, National Breast and Cervical Cancer Early Detection Program, CDC*
11:40 a.m. - 12:00 p.m.	Currently Available Diagnostics *Mark Schiffman, MD, MPH, Division of Cancer Epidemiology and Genetics, NCI*
12:00 p.m. - 12:10 p.m.	Break

12:10 p.m. - 12:30 p.m.	Hurdles from Design to Evaluation of Intervention (e.g. biological, technical, regulatory, cost and reimbursement) *Philip Castle, PhD, Director, Division of Cancer Prevention, NCI*
12:30 p.m. - 12:50 p.m.	Opportunities from design to implementation and evaluation of intervention strategies for the use of cancer diagnostic devices in populations experiencing health disparities and health inequities *Erin Kobetz, PhD, MPH, University of Miami*
12:50 p.m. - 1:50 p.m.	 Lunch

SESSION II: Remarks from Senior Leadership

1:50 p.m. - 2:20 p.m.	To speak on the Initiative • *Douglas R. Lowy, MD, Principal Deputy Director, NCI* To speak on the MOU and its significance • *Norman Sharpless, MD, Director, NCI* • *Anand Shah, MD, Deputy Commissioner for Medical and Scientific Affairs, Office of the Commissioner, FDA* • *Diana Espinosa, Deputy Administrator, HRSA (pending confirmation; invitation sent)* • *CMS leadership representative: TBD* *<<Virtual Group Photo - all participants>>*
2:20 p.m. - 2:30 p.m.	 Break

SESSION III: State of the Science - Liver Cancer

2:30 p.m. - 2:35 p.m.	Session Introduction *Session Chair: Fasiha Kanwal, MD, MSHS, AGAF, Baylor College of Medicine*
2:35 p.m. - 2:55 p.m.	The Evolving Clinical Course of Liver Disease and Emerging Trends for the Etiology of Hepatocellular Carcinoma *Lara Dimick-Santos, MD, Center for Drug Evaluation and Research, FDA*
2:55 p.m.- 3:15 p.m.	Needs for Bringing Liver Disease Screening Platforms Out of Hospital and to Patients *Xin Wei Wang, PhD, Center for Cancer Research, NCI*
3:15 p.m. - 3:25 p.m.	 Break
3:25 p.m. - 3:45 p.m.	Current Diagnostic Strategies for Hepatocellular Carcinoma and Emerging Near-patient Earlier Detection Platforms *Shan Wang, PhD, Stanford University*
3:45 p.m. - 4:05 p.m.	Current Clinical and Emerging Markers for Liver Disease (e.g., fibrosis, physiology, comorbidity) that Could Guide Patient Stratification and Risk *Rohit Loomba, MD, University of California, San Diego*

4:05 p.m. - 4:15 p.m.	Questions
4:15 p.m. - 4:20 p.m.	Wrap-up / Closing Remarks *Robin Vanderpool, Dr.P.H., Division of Cancer Control and Population Sciences, NCI*

DAY 2: Friday, October 9, 2020 (10:00 a.m. – 3:35 p.m.)

10:00 a.m. - 10:30 a.m.	Join the meeting / Computer check
10:30 a.m. - 10:40 a.m.	Welcome, Online etiquette Rules, and Charge for the Day *Christopher Hartshorn, PhD, Division of Cancer Treatment and Diagnosis, NCI* *Henry Rodriguez, PhD, MBA, Office of Cancer Clinical Proteomics Research, NCI* *Sonia Rosenfield, PhD, Center for Research Strategy, NCI* *Ashim Subedee, PhD, Small Business Innovation Research, NCI* *Robin Vanderpool, Dr.P.H., Division of Cancer Control and Population Sciences, NCI* *Živana Težak,PhD, Center for Devices and Radiological Health, FDA* *Sabrina Matoff-Stepp, PhD, Office of Planning, Analysis, and Evaluation, HRSA* *Susan Monarez, PhD, Office of Planning, Analysis and Evaluation, HRSA* *Sarah Harding, Division of Ambulatory Services, CMS*

SESSION I: Case studies

10:40 a.m. – 11:05 a.m.	Introduction Overview of the different types of near patient diagnostics, approvals, and expectations *Session Chair: Marina V. Kondratovich, PhD, Center for Devices and Radiological Health, FDA*
11:05 a.m. - 11:25 a.m.	OncoE6™ Cervical Cancer Test (CE Mark and available in the US, as a service throughour CLIA-certified laboratory) *Johannes Schweizer, Arbor Vita, Fremont, CA*
11:25 a.m. - 11:35 a.m.	 Break
11:35 a.m. - 11:55 a.m.	Cologuard Colon Cancer Screening Test (FDA approved) *Graham Lidgard, Exact Sciences Corporation, Madison, WI*
11:55 a.m. - 12:05 p.m.	Questions
12:05 p.m. - 1:00 p.m.	 Lunch

SESSION II: World Café Breakout Groups

1:00 p.m.- 1:05 p.m.	Introduction to the World Café Process: 3 Discussion Questions (one for each round)

- Question #1: Barriers and Challenges Theme – What are major barriers and challenges to bringing CD2 for near patient use in geographically isolated, medically underserved, and otherwise vulnerable communities?
  Facilitator: Anand Pathak, PhD, MD, MPH, Center for Devices and Radiological Health, FDA; Notetaker: Tara Hiltke, PhD, Office of Cancer Clinical Proteomics Research, NCI
- Question #2: Opportunities and Action Items Theme – What are the opportunities (i.e. facilitators, resources) to streamline/accelerate CD2 from design to implementation in these communities?
  Facilitator: LeeAnn Bailey, PhD, Center to Reduce Cancer Health Disparities, NCI; Notetaker: Rao Divi, Division of Cancer Control and Population Sciences, NCI
- Question #3: Progress through Collaboration Theme — How can the Federal partners support, incentivize and promote CD2 developers?
  Facilitator: Sabrina Matoff-Stepp, PhD, Office of Planning, Analysis, and Evaluation, HRSA; Notetaker: Tiffany Gillis-Brown, JD, HRSA

1:05 p.m.- 1:15 p.m.	Room Transition / Break
1:15 p.m.- 1:45 p.m.	World Café Session #1
1:45 p.m.- 1:55 p.m.	Room Transition / Break
1:55 p.m.- 2:15 p.m.	World Café Session #2
2:15 p.m.- 2:25 p.m.	Room Transition / Break
2:25 p.m.- 2:45 p.m.	World Café Session #3
2:45 p.m.- 2:55 p.m.	Room Transition /Break
2:55 p.m.- 3:25 p.m.	World Café, Reporting Out *Anand Pathak (FDA), LeeAnn Bailey (NCI), Sabrina Matoff-Stepp (HRSA)*
3:25 p.m.- 3:35 p.m.	Next Steps and Closing remarks *Henry Rodriguez, PhD, MBA, Director* *Office of Cancer Clinical Proteomics Research, NCI*