FDA Public Meeting: Identification of Concepts and Terminology for Multi-Component Biomarkers

Virtual Public Workshop
March 23 - 24
1-3 PM (ET)

AGENDA:

The FDA Center for Drug Evaluation and Research and the FDA Biomarker Working Group will convene a virtual workshop on March 23-24, 2022, 1-3 PM (ET) with title “Identification of Concepts and Terminology for Multi-Component Biomarkers”. The workshop is intended to develop multi-component biomarker concepts and terminology, to identify areas of conceptual language development through presentation of use cases, and discuss gaps in terminology for concepts and approaches related to multi-component biomarkers. You can find more information on the goals and objectives of the symposium here.

The symposium will be accessible to the public via live webcast. Please register online to receive an email with the instructions on how to join this event. Additionally, there are pre-recorded talks that will be available to the public three weeks prior to the live event, and participants are highly encouraged to view the presentations before attending the live discussions.

Pre-recorded introduction to multi-component biomarkers and biomarker terminology

10 minutes	**Introduction by the FDA Biomarker Working Group Co-chairs** **Multi-component biomarkers - Set the stage for the other sessions (where we are, where we are going)** Daniel Krainak (FDA/ CDRH) and Abena Agyeman (FDA/CDER)
45 minutes	**Keynote lecture** **Multi-Component Biomarkers: Promise, Practice and Perspective on Terminology** John Wagner, MD, PhD. Chief Medical Officer at Koneksa Health
10 minutes	**BEST: A Resource for Effective Communication** Lisa McShane, PhD, Chief, Biometric Research Program, National Cancer Institute, NIH
20 minutes	**Biomarkers and Drug Development: A Regulatory Perspective** Jeffrey Siegel, MD, Director, Office of Drug Evaluation Sciences (FDA/ CDER)
30 minutes	**Multi-markers in Test Evaluation** Patrick Bossuyt, PhD, Professor of Clinical Epidemiology, Biomarker and Test Evaluation Research Program, University of Amsterdam

Pre-recorded talks of biomarker in clinical setting

20 minutes	***Prognostic & Predictive Biomarkers for Detection of Early/Acute HIV-1 Infection*** Krishnakumar Devadas, PhD, Staff Scientist, Laboratory of Molecular Virology (FDA/ CBER)
20 minutes	***Predictive Biomarker Homologous Recombination Deficiency (HRD) in Ovarian Cancer*** Francisca Reyes Turcu, PhD, Senior Scientific Reviewer (FDA/ CDRH)
20 minutes	***iBox Scoring System: A composite surrogate for long-term graft loss after kidney transplantation*** Amanda Klein, PharmD CDCES, Interim Executive Director, Transplant Therapeutics Consortium (C-Path)
20 minutes	***Prognostic Biomarker for the Enrichment/Identification of Subjects with Knee Osteoarthritis*** Steve Hoffmann, Associate Vice president for Research and Partnership, FNIH Biomarker Consortium
20 minutes	***Biomarker Test to Assess Likelihood of Progression to Cirrhosis or Clinical Outcomes in Patients with Advanced Fibrosis due to Non-Alcoholic Steatohepatitis (NASH)*** Irene Tebbs, PhD, Scientific Reviewer (FDA/ CDRH)
20 minutes	***Biomarkers to Identify Exposure to Harmful or Potentially Harmful Constituents in Tobacco Smoke*** Stephen Hecht, PhD, Wallin Land Grant Professor of Cancer Prevention, University of Minnesota

Live Virtual Discussion

(4 hours total: 2 hours on Day 1; 2 hours on Day 2)

Day 1 March 23rd,2022

15 minutes 1:00 – 1:15	**Introduction Day 1 – Setting the Stage/ Highlights of the Background Talks** BWG co-chairs Daniel Krainak (FDA/CDRH) and Abena Agyeman (FDA/CDER)
5 minutes 1:15 – 1:20	**Summary of *Prognostic & Predictive Biomarkers for Detection of Early/Acute HIV-1 Infection*** Krishnakumar Devadas, PhD, Staff Scientist, Laboratory of Molecular Virology (FDA/ CBER)

5 minutes 1:20 – 1:25	**Summary of *Predictive Biomarker Homologous Recombination Deficiency (HRD) in Ovarian Cancer*** Francisca Reyes Turcu, PhD, Senior Scientific Reviewer, (FDA/ CDRH)
30 minutes 1:25 – 1:55	***Panel Discussion 1 – Fluid Biomarkers 1 and Comments*** **Moderator**: Abbas Bandukwala (FDA/ CDER) **Panelists:** Robert Schuck (FDA/ CDER), Krishnakumar Devadas (FDA/ CBER), Francisca Reyes Turcu, PhD (FDA/ CDRH), Nicholas King (C-Path)
5 minutes 2:00 – 2:05	**Summary of** Biomarker Test to Assess Likelihood of Progression to Cirrhosis or Clinical Outcomes in Patients with Advanced Fibrosis due to Non-Alcoholic Steatohepatitis (NASH) Irene Tebbs, PhD, Scientific Reviewer (FDA/ CDRH)
5 minutes 2:05 – 2:10	**Summary of *Biomarkers to Identify Exposure to Harmful or Potentially Harmful Constituents in Tobacco Smoke*** Stephen Hecht, PhD, Wallin Land Grant Professor of Cancer Prevention, University of Minnesota
30 minutes 2:10 – 2:40	***Panel Discussion 2 – Fluid Biomarkers 2 and Comments*** **Moderator:** Theresa Thekkudan (FDA/CTP) ***Panelists:*** Irene Tebbs (FDA/ CDRH), Stephen Hecht (Univ. of Minnesota), Cindy Chang (FDA/ CTP), Kellie Kelm (FDA/ CDRH)
15 minutes 2:40 – 2:55	***Wrap up Day 1***

Day 2 March 24th, 2022

5 minutes 1:00 – 1:05	**Introduction Day 2 – Brief summary of Day 1, reminder of goals for workshop** BWG co-chairs Daniel Krainak (FDA/ CDRH) and Abena Agyeman (FDA/CDER)
5 minutes 1:05 – 1:10	***Summary of iBox Scoring System: A composite surrogate for long-term graft loss after kidney transplantation*** Amanda Klein, PharmD CDCES, Interim Executive Director, Transplant Therapeutics Consortium (C-Path)
5 minutes 1:10 – 1:15	***Summary of Prognostic Biomarker for the Enrichment/Identification of Subjects with Knee Osteoarthritis*** Steve Hoffmann, Associate Vice president for Research and Partnership, FNIH Biomarker Consortium
30 minutes 1:15 – 1:45	***Panel Discussion 3 and Comments*** **Moderator**: Abena Agyeman (FDA/ CDER)

	Panelists: Jeffrey Siegel (FDA/ CDER), Steve Hoffmann (FNIH), Nicholas King (C-Path), Klaus Romero (C-Path), Daniel Krainak (FDA/ CDRH), Soma Ghosh (FDA/ CDRH), Amanda Klein (C-PATH)
5 minutes 1:45 – 1:50	**Summary Panel Discussion 1 - Fluid Biomarkers 1** Abbas Bandukwala (FDA/ CDER)
5 minutes 1:50 – 1:55	**Summary Panel Discussion 2 - Fluid Biomarkers 2** Theresa Thekkudan (FDA/CTP)
5 minutes 1:55 – 2:00	**Summary Panel Discussion 3 – Imaging Biomarkers** Abena Agyeman (FDA/ CDER)
45 minutes 2:00 – 2:45	***Common Themes and Concepts Panel Discussion and Comments*** **Moderator**: Sue-Jane Wang (FDA/CDER) ***Panelists:*** Patrick Bossuyt (Univ. of Amsterdam), Steve Hoffman (FNIH), Samir Lababidi (FDA/OC), Phillip Turfle (FDA/ CVM); Lisa McShane (NCI/NIH), John Wagner (Koneksa Health)
15 minutes 2:45 – 3:00	**Workshop Wrap-up & Next Steps** Jeffrey Siegel (FDA/ CDER)