FDA-AACR Real-world Evidence Workshop

July 19, 2019

Bethesda Doubletree by Hilton | Bethesda, MD

Workshop Cochairs:

U.S. Food and Drug Administration:

Sean Khozin, MD, MPH, Associate Director, Oncology Center of Excellence, Director, Information Exchange and Data Transformation (INFORMED), U.S. Food and Drug Administration

Pallavi Mishra-Kalyani, PhD, Team Leader, Division of Biometrics V, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

American Association for Cancer Research:

Deborah Schrag, MD, MPH, Chief, Division of Population Sciences, Dana-Farber Cancer Institute

AGENDA

INTRODUCTION

8:00 AM **Introduction & Objectives**
Workshop cochair

SESSION I: INTRO TO REAL-WORLD EVIDENCE

This session will introduce real-world evidence concepts and the utility of using real-world data sources.

8:05 AM **Keynote: FDA Framework on Real-world Evidence**
Jacqueline Corrigan-Curay, JD, MD, U.S. Food and Drug Administration

8:45 AM **Intro to RWE - utility, clinical decision support**
Elad Sharon, MD, MPH, National Cancer Institute

SESSION II: PREMARKET USE CASES
SESSION MODERATOR: PALLAVI MISHRA-KALYANI, PHD

This session will provide examples of using real-world evidence in drug development.

9:05 AM **Michael Kelsh, PhD, MPH,** Amgen

9:25 AM **William Capra, PhD,** Genentech

9:45 AM **Weili He, PhD,** AbbVie

10:05 AM **PANEL DISCUSSION and AUDIENCE Q&A**

Panelists: **Session II speakers and the following additional panelists:**
Rajeshwari Sridhara, PhD, U.S. Food and Drug Administration

10:35 AM **BREAK**

SESSION III: POSTMARKET USE CASES
SESSION MODERATOR: PALLAVI MISHRA-KALYANI, PHD

This session will provide examples of using real-world evidence in postmarket situations.

10:55 AM **Albert L. Kraus, PhD,** Pfizer

11:15 AM **Ruthanna Davi, PhD,** Medidata Solutions

11:35 AM **Jeff Allen, PhD,** Friends of Cancer Research

11:55 AM **PANEL DISCUSSION and AUDIENCE Q&A**

Panelists: **Session III speakers and the following additional panelists:**
Mark Levenson, PhD, U.S. Food and Drug Administration
Frank W. Rockhold, PhD, Duke Clinical Research Institute

12:20 PM **LUNCH (ON YOUR OWN)**

SESSION IV: LARGE GENOMIC DATABASES & REAL-WORLD EVIDENCE
SESSION MODERATOR: DEBORAH SCHRAG, MD, MPH

This session will explore large genomic databases and digital data as real-world sources of information.

1:20 PM **ASCO CancerLinQ**
Wendy Rubinstein, MD, PhD, CancerLinQ

1:32 PM **The NCI Genomic Data Commons and Cancer Research Data Commons and Real-world Data**
Robert Grossman, PhD, University of Chicago

1:44 PM **ORIEN**
William S. Dalton, PhD, MD, M2Gen

1:56 PM **Flatiron Health**
Neal Meropol, MD, Flatiron Health

2:08 PM **Tempus**
Gary Palmer, MD, Tempus

2:20 PM **Syapse**
Jonathan Hirsch, Syapse

2:32 PM **AACR GENIE**
Deborah Schrag, MD, MPH, Dana-Farber Cancer Institute

2:44 PM **PANEL DISCUSSION and AUDIENCE Q&A**

Panelists: **Session IV speakers**

3:05 PM **BREAK**

SESSION V: REAL-WORLD EVIDENCE - FUTURE DIRECTIONS
SESSION MODERATOR: ERIC PERAKSLIS, PHD

This session will explore the future of real-world evidence.

3:20 PM	**Digital Health Technology** **Andrea Coravos,** Elektra Labs
3:35 PM	**Digital Phenotyping** **James Gulley, MD, PhD,** National Cancer Institute
3:50 PM	**Perpetual Trials** **Mark Shapiro, MBA, PhD,** xCures
4:05 PM	**PANEL DISCUSSION and AUDIENCE Q&A**
Panelists:	**Session V speakers and the following additional panelists:** **Pallavi Mishra-Kalyani, PhD,** U.S. Food and Drug Administration **Deborah Schrag, MD, MPH,** Dana-Farber Cancer Institute **Oliver Bogler, PhD,** ECHO Institute **Rohit Borker, PhD,** Novartis
4:55 PM	**Wrap up: Summary** **Workshop cochair**
5:00 PM	**ADJOURN**