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

9:05 AM Mike 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

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Join the conversation with #OCEAACRRWE
SESSION III: POSTMARKET USE CASES
SESSION MODERATOR: TBD
This session will provide examples of using real-world evidence for postmarket surveillance.

10:55 AM Ruthanna Davi, PhD, Medidata Solutions
11:15 AM Cynthia Huang, MD, Pfizer
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

12:25 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.

1:25 PM AACR GENIE
Deborah Schrag, MD, MPH, Dana-Farber Cancer Institute

1:35 PM ASCO CancerLinQ
Wendy Rubinstein, MD, PhD, CancerLinQ

1:45 PM NCI Genomic Data Commons & Cancer Research Data Commons
Robert Grossman, PhD, University of Chicago

1:55 PM ORIEN
William S. Dalton, PhD, MD, M2Gen

2:05 PM Flatiron Health
Neal Meropol, MD, Flatiron Health

2:15 PM Tempus
Gary Palmer, MD, Tempus

2:25 PM PANEL DISCUSSION and AUDIENCE Q&A
Panelists: Session IV speakers and the following additional panelists:
Jonathan Hirsch, Syapse

2:55 PM BREAK

SESSION V: REAL-WORLD EVIDENCE - FUTURE DIRECTIONS
SESSION MODERATOR: TBD
This panel session will discuss the future of real-world evidence.
3:05 PM  Digital Health Technology  
Andrea Coravos, Elektra Labs

3:25 PM  Digital Phenotyping  
James Gulley, MD, PhD, National Cancer Institute

3:45 PM  FDA Perspective

4:15 PM  PANEL DISCUSSION and AUDIENCE Q&A

Moderators:
Panelists: Session V speakers and the following additional panelists:
   Sean Khozin, MD, MPH, U.S. Food and Drug Administration
   Pallavi Mishra-Kalyani, PhD, U.S. Food and Drug Administration
   Deborah Schrag, MD, MPH, Dana-Farber Cancer Institute

4:55 PM  Wrap up: Summary  
Workshop cochair

5:00 PM  ADJOURN