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 Presentation: FDA Framework on RWE, etc.
8:45 AM Intro to RWE- utility, clinical decision support

SESSION II: PREMARKET USE CASES
SESSION MODERATOR: TBD
This session will provide examples of using real-world evidence in drug development.
9:05 AM TBD
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, FDA

10:35 AM BREAK

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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
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 University

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  Stakeholder

2:15 PM  Stakeholder

2:25 PM  PANEL DISCUSSION and AUDIENCE Q&A
Panelists: Session IV speakers

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  FDA Digital Health Framework

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<th>Time</th>
<th>Session</th>
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<tr>
<td>3:25 PM</td>
<td>Digital Phenotyping&lt;br&gt;James Gulley, MD, PhD, Center for Cancer Research, NCI, NIH</td>
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<tr>
<td>3:45 PM</td>
<td>FDA Perspective</td>
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<td>4:15 PM</td>
<td>PANEL DISCUSSION and AUDIENCE Q&amp;A&lt;br&gt;Moderators: Session V speakers and the following additional panelists:&lt;br&gt;Sean Khozin, MD, MPH&lt;br&gt;Pallavi-Mishra Kalyani, PhD&lt;br&gt;Deborah Schrag, MD, MPH</td>
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<td>4:55 PM</td>
<td>Wrap up: Summary&lt;br&gt;Workshop cochair</td>
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