# 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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Content</th>
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| 8:00 AM | Introduction & Objectives  
Workshop cochair                                                                 |
| 8:05 AM | **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 |
| 9:05 AM | **SESSION II: PREMARKET USE CASES**  
SESSION MODERATOR: PALLAVI MISHRA-KALYANI, PHD |
| 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 |

@FDAOncology @AACR

Join the conversation with #OCEAACRRWE
**SESSION III: POSTMARKET USE CASES**  
**SESSION MODERATOR: PALLAVI MISHRA-KALYA, PHD**

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

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<tr>
<th>Time</th>
<th>Speaker and Title</th>
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<tbody>
<tr>
<td>10:55 AM</td>
<td>Albert L. Kraus, PhD, Pfizer</td>
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<tr>
<td>11:15 AM</td>
<td>Ruthanna Davi, PhD, Medidata Solutions</td>
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<tr>
<td>11:35 AM</td>
<td>Jeff Allen, PhD, Friends of Cancer Research</td>
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**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.

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| 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.*

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<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>3:20 PM</td>
<td>Digital Health Technology</td>
<td>Andrea Coravos, Elektra Labs</td>
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<td>3:35 PM</td>
<td>Digital Phenotyping</td>
<td>James Gulley, MD, PhD, National Cancer Institute</td>
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<td>3:50 PM</td>
<td>Perpetual Trials</td>
<td>Mark Shapiro, MBA, PhD, xCures</td>
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| 4:05 PM| PANEL DISCUSSION and AUDIENCE Q&A    | 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                               |                                             |