



# Regulatory Science and Policy Track

All times are listed in Pacific Daylight Time (PDT)

## SATURDAY, APRIL 18

10:00 a.m.-11:30 a.m.

### Advancing Patient-Centered Clinical Trials: Bringing Trials to Patients and Patients to Trials

**Roy S. Herbst**, *Moderator*, Yale Cancer Center, New Haven, CT; **Robert A. Winn**, VCU Massey Comprehensive Cancer Center, Richmond, VA; **Patricia M. LoRusso**, Yale University, New Haven, CT; **Konstantin H. Dragnev**, Dartmouth-Hitchcock, Lebanon, VT; **Electra D. Paskett**, The Ohio State University, Columbus, OH; **Camille Campbell**, Biogen, MD

12:30 p.m.-2:00 p.m.

### Where Expedited Pathways, Innovation, Safety, and Patient Access Collide: A KRAS Case Study

**Elizabeth M. Jaffee**, *Moderator*, Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD; **Timothy A. Yap**, *Moderator*, UT MD Anderson Cancer Center, Houston, TX; **Ignacio Garrido-Laguna**, University of Utah Huntsman Cancer Institute, Salt Lake City, UT; **Andrew Rakeman**, Lustgarten Foundation, Woodbury, NY; **Lola A. Fashoyin-Aje**, Consultant, Silver Spring, MD; **Cristian Massacesi**, Bristol Myers Squibb; **Mark Wicclair**, University of Pittsburgh, Pittsburgh, PA

2:30 p.m.-4:00 p.m.

### Contextual Challenges in Interpreting Performance of Blood-Based Early Cancer Detection Tests

**Christina Clarke Dur**, *Co-Moderator*, GRAIL, Inc., Menlo Park, CA; **Bree L. Mitchell**, *Co-Moderator*, Natera, San Carlos, CA; **Nima Nabavizadeh**, *Co-Moderator*, Portland, OR; **Aasma Shaukat**, *Co-Moderator*, NYU Langone, New York, NY; **Robert A. Smith**, *Co-Moderator*, American Cancer Society, Atlanta, GA; **Anand Pathak**, *Co-Moderator*, U.S. Food and Drug Administration, Silver Spring, MD; **Gary Puckrein**, *Co-Moderator*, National Minority Quality Forum, Washington, DC

## SUNDAY, APRIL 19

1:00 p.m.-2:30 p.m.

### Approaches to Drug Development for Rare Malignancies

**Elizabeth Dianne Pulte**, *Moderator*, U.S. Food & Drug Administration, Silver Spring, MD; **Martha Donoghue**, U.S. Food and Drug Administration, Silver Spring, MD; **Eric Padron**, Moffitt Cancer Center, Tampa, FL; **Rachel N. Grisham**, Memorial Sloan Kettering Cancer Center, New York, NY; **Stephanie Wethington**, U.S. Food and Drug Administration, Silver Spring, MD; **Joshua H. Bilenker**, Treeline Biosciences, Watertown, MA; **Denise K. Reinke**, University of Michigan, Ann Arbor, MI; **Nicole Andrews**, STAAR, Chicago, IL

4:30 p.m.-6:00 p.m.

### Modernizing Nonclinical Safety Assessment in Oncology Product Development: Current Progress and Future Directions

**Haleh Saber**, *Moderator*, U.S. Food and Drug Administration, Silver Spring, MD; **Michael Manning**, U.S. Food and Drug Administration, Silver Spring, MD; **Natalie E. Simpson**, U.S. Food and Drug Administration, Silver Spring, MD; **Matthew Thompson**, U.S. Food and Drug Administration, Silver Spring, MD; **Tiffany Ricks**, U.S. Food and Drug Administration, Silver Spring, MD; **Jacintha Shenton**, Amgen, Thousand Oaks, CA; **Shannon M. Mumenthaler**, Ellison Medical Institute, Duarte, CA; **Rodney Prell**, Genentech, South San Francisco, CA

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## Regulatory Science and Policy Track *(cont'd)*

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### MONDAY, APRIL 20

10:15 a.m.-11:45 a.m.

#### Strengthening the Oncology Trial Ecosystem Through Operational and Regulatory Innovation

**Lola A. Fashoyin-Aje**, *Moderator*, Consultant, Silver Spring, MD; **Mark D. Stewart**, Friends of Cancer Research, Washington, DC; **Jason Lebsack**, Moffitt Cancer Center, Tampa, FL; **Judith A. Fitzgerald**, Sisters4Prevention, West Palm Beach, FL; **Terrell Baptiste**, Gilead, San Francisco, CA; **Bea Lavery**, Genentech, Inc.

2:15 p.m.-3:45 p.m.

#### Advancing Early-Phase Pediatric Cancer Trials to Turn Promising Agents into Actionable Evidence

**Meredith S. Irwin**, *Chairperson*, SickKids, Toronto, ON, Canada; **Brenda J. Weigel**, St. Jude Children's Research Hospital, Memphis, TN; **Nicole Drezner**, FDA, Silver Spring, MD; **Gerard McGeehan**, Syndax Pharmaceuticals, Inc., Newtown Square, PA

4:00 p.m.-5:30 p.m.

#### Power in Numbers: Leveraging Adult Data in Pediatric Cancer Drug Development

**Martha Donoghue**, *Moderator*, U.S. Food and Drug Administration, Silver Spring, MD; **Nicole Drezner**, U.S. Food and Drug Administration, Silver Spring, MD; **Mansi Dalal**, U.S. Food and Drug Administration, Silver Spring, MD; **Lauren Price**, U.S. Food and Drug Administration, Silver Spring, MD; **Jiang Liu**, U.S. Food and Drug Administration, Silver Spring, MD; **Adam Levy**, Bristol Myers Squibb, Princeton, NJ; **Vickie Buenger**, Coalition Against Childhood Cancer, Bryan, TX

### TUESDAY, APRIL 21

12:30 p.m.-2:00 p.m.

#### Code Meets Cure: Navigating the Regulatory Landscape of AI in Oncology Drug Development

**Jeevan Puthiamadathil**, *Moderator*, Food and Drug Administration, Silver Spring, MD; **Anindita Saha**, Food and Drug Administration, Silver Spring, MD; **Carlos Sandi**, St. Baldrick's Foundation, Monrovia, CA; **Jorge S. Reis-Filho**, AstraZeneca US, Gaithersburg, MD

## Science and Health Policy Track

### SUNDAY, APRIL 19

3:00 p.m.-4:30 p.m.

#### Researcher Town Hall: Navigating Policy Challenges and Securing Funding

**Roy S. Herbst**, *Moderator*, Yale Cancer Center, New Haven, CT; **E. John Wherry**, University of Pennsylvania, Philadelphia, PA; **Patricia Spears**, UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC; **Jon G. Retzlaff**, American Association for Cancer Research®, Washington, DC; **Cornelia Ulrich**, Huntsman Cancer Institute, Salt Lake City, UT

### MONDAY, APRIL 20

12:30 p.m.-2:00 p.m.

#### Cancer Prevention and Screening: Exploring Policy Solutions

**Gilbert S. Omenn**, *Moderator*, University of Michigan, Ann Arbor, MI; **Suchitra Krishnan-Sarin**, Yale University School of Medicine, New Haven, CT; **Timothy Rebbeck**, Dana-Farber Cancer Institute, Boston, MA; **Electra D. Paskett**, The Ohio State University, Columbus, OH; **Philip E. Castle**, National Cancer Institute, Rockville, MD; **Douglas E. Wood**, University of Washington, Seattle, WA

2:30 p.m.-3:45 p.m.

#### NCI Director's Address and Fireside Chat with AACR Leaders

Ballroom 6 A - Upper Level - Convention Center

**Anthony G. Letai**, National Cancer Institute, Bethesda, MD

#### FIRESIDE CHAT

**Lillian L. Siu**, UHN Princess Margaret Cancer Centre, Toronto, ON, Canada; **Keith Thomas Flaherty**, Mass General Cancer Center, Cambridge, MA



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