



FDA Public Workshop: Oncology Center of Excellence...Envisioning Oncology Product Development for 2025

Twitter: [#OCEProject2025](https://twitter.com/OCEProject2025)

February 5, 2020

FDA White Oak Campus, Great Room

AGENDA

8:30 am – 8:45 am **Keynote Address: Cancer Care 2025**..... Ned Sharpless

8:45 am – 9:00 am **Introductory Remarks**..... Richard Pazdur

9:00 am – 10:00 am **Session 1: OCE Regulatory Innovation**
Moderator: Richard Pazdur

- Regulatory Review Pilots: RTOR, Assessment Aid..... Marc Theoret
- Project Renewal..... Paul Kluetz
- Project Orbis.....Dianne Spillman
- OCE and CBER “MORE” Teams..... Ke Liu

Panelists:

- Tamy Kim, OCE Regulatory Affairs
- Katie Thornton, Dana Farber Cancer Center
- Rich Moscicki, PhRMA
- Jean-Francois Ethier, Reviewer, Health Canada
- Andrea Ferris, LUNgevity

10:00 am – 10:15 am **BREAK**

10:15 am – 11:15 am **Session 2: OCE Novel Patient-Focused Drug Development Initiative**
Moderators: Paul Kluetz and Wendy Rubinstein

- OCE Pediatric Program.....Martha Donoghue
- Project Facilitate.....Jessica Boehmer
- OCE Patient-Focused Drug Development Program.....Vishal Bhatnagar

Panelists:

- Nancy Goodman, Kids v. Cancer
- Thomas Rice, Legislative Assistant to Congressman McCaul
- Paul Papagni, Executive Director of Research, Holy Cross Hospital, Florida
- Caroline Schenkel, ASCO-FOCR Eligibility Criteria Working Groups
- Patty Spears, Patient Advocate

11:15 am – 11:30 am **BREAK**

11:30 am – 12:15 pm **Session 3: OCE Science, Education, and Outreach**

Moderator: Rea Blakey

- Project Community.....Rea Blakey
- Project Socrates..... Jennifer Gao
- OCE Funding and Internal Scientific Effort.....Julie Schneider

Panelists:

- Piyush Srivastava, Medical Oncologist, Kaiser Permanente
- Jon Retzlaff, Chief Policy Officer, VP Science Policy and Government Affairs, AACR
- Jessica Hawley, Oncology Fellow, Columbia University
- Stephanie Kaplan, Deputy Director Government relations and Public Health, ASH

12:15 pm – 12:55 pm **Session 4: Recommendations for OCE by 2025**

Moderator: Rick Pazdur

Panelists:

- Ellen Sigal, Chairperson and Founder, Friends of Cancer Research
- Representative from U.S. Representative Fred Upton’s Office
- Representative from U.S. Representative Diana DeGette’s Office

12:55 pm – 1:00 pm **Closing** Richard Pazdur