

**Defining a Research Agenda to Address Barriers and Solutions to Oral Anticancer Agent Adherence:
An ASCO-FDA Workshop**

Date: February 2-3, 2021
Virtual Meeting

	Day 1: February 2, 2021
1:00-1:15	<p>Welcome to the Workshop</p> <ul style="list-style-type: none"> • R. Donald Harvey, Emory School of Medicine, Workshop Co-Chair • Shaily Arora, U.S. Food and Drug Administration, Workshop Co-chair
1:15-2:45	<p>Session 1: Drug Development and Clinical Pharmacology</p> <p>Topics:</p> <ol style="list-style-type: none"> (1) Formulation (2) Schedule and duration of therapy (3) Dose derivation process, including dose optimization (4) Interactions - polypharmacy (5) Labeling – risk mitigation (6) Adherence in other settings <p>Moderator: Atik Rahman, U.S. Food and Drug Administration</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Julie Bullock, Certara • Anthony Tolcher, NEXT Oncology San Antonio • Mark Ratain, University of Chicago • Charles W. Flexner, Johns Hopkins School of Medicine <p>Panelists (will also include speakers):</p> <ul style="list-style-type: none"> • Patty Spears, UNC Lineberger Comprehensive Cancer Center • Michelle Miller, Novartis <p>Question and Answer</p>
2:45-3:00	Break

<p>3:00-4:30</p>	<p>Session 2: Trial Design, Adverse Event Reporting, and Translation of Information</p> <p>Topics:</p> <ol style="list-style-type: none"> (1) Patient and provider perspective on adherence and tolerability (2) What does adherence look like in the “real-world”? (3) Measuring “tolerability” in cancer trials (4) Communicating tolerability to patients and providers <p>Moderator: Paul Kluetz, U.S. Food and Drug Administration</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Lee Jones, cancer research advocate • David Waterhouse, U.S. Oncology • Kelly Brassil, Pack Health • Vishal Bhatnagar, FDA Oncology Center of Excellence • Serban Ghiorghiu, AstraZeneca <p>Question and Answer</p>
<p>4:30</p>	<p>Adjourn Day 1</p>

<p>Defining a Research Agenda to Address Barriers and Solutions to Oral Anticancer Agent Adherence: An ASCO-FDA Workshop</p> <p>Date: February 2-3, 2021 Virtual Meeting</p>	
<p>Day 2: February 3, 2021</p>	
<p>1:00-1:15</p>	<p>Welcome to the Workshop</p> <p>Shaily Arora, U.S. Food and Drug Administration, Workshop Co-chair</p>

<p>1:15-2:45</p>	<p>Session 3: Social Determinants of Adherence</p> <p>Topics:</p> <ol style="list-style-type: none"> (1) Patient characteristics (e.g., literacy, language, motivation) (2) Patient-health care provider relationships (e.g., trust/perception, time to communicate, teaching method, learning style) (3) Community characteristics (e.g., access to transportation, food, social support; exposure to discrimination, stigma, etc.) (4) Health Economics (e.g., co-pays and coverage policies) <p>Moderator: Rea Blakey, FDA</p> <p>Panelists for Moderated Discussion:</p> <ul style="list-style-type: none"> • Dana Deighton, esophageal cancer survivor • Chanita Hughes Halber, Medical University of South Carolina • Benyam Muluneh, UNC Eshelman School of Pharmacy • Ifeyinwa Osunkwo, Atrium Health • Ann Partridge, Dana-Farber Cancer Institute • Susan Schneider, Duke University School of Nursing <p>Question and Answer</p>
<p>2:45-3:00</p>	<p>Break</p>
<p>3:00-4:00</p>	<p>Session 4a: Adherence in Special Populations: Adolescent and Young Adult Case Study</p> <p>Topics: Fertility concerns and sexual dysfunction; medical marijuana; developmental and psychological issues</p> <p>Moderator: Margaret Thompson, U.S. Food and Drug Administration</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Emily Drake, Adolescent and Young Adult Cancer Societal Movement (#AYACSM) • Gwendolyn P. Quinn, NYU Grossman School of Medicine • Stefanie Thomas, Cleveland Clinic • Samuel Takvorian, University of Pennsylvania Perelman School of Medicine <p>Question and Answer</p>
<p>4:00-4:15</p>	<p>Break</p>

<p>4:15-5:15</p>	<p>Session 4b: Adherence in Special Populations: Older Adults Case Study</p> <p>Topics:</p> <ol style="list-style-type: none"> (1) Barriers to oral adherence most relevant to the older adult population, (2) intervention strategies to support oral adherence for older adults (3) Considerations for therapeutic clinical trial design for oral therapies in the older adult population <p>Moderator: Allison Magnuson, University of Rochester</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Chuck O’Shea, Patient advocate and caregiver • Manvi Sharma, University of Mississippi • Erika E. Ramsdale, University of Rochester • Dany Habr, Pfizer Oncology <p>Question and Answer</p>
<p>5:15-5:30</p>	<p>Closing Remarks</p> <ul style="list-style-type: none"> • R. Donald Harvey, Emory School of Medicine, Workshop Co-Chair • Shaily Arora, U.S. Food and Drug Administration, Workshop Co-Chair
<p>5:30</p>	<p>Adjourn</p>