

Measuring Toxicity in Reproductive Organs During Oncology Drug Development

An FDA-ASCO Virtual Workshop

October 1 and 8, 2024

Day 1: October 1, 2024	
1:00	<p>Introduction to the Workshop</p> <ul style="list-style-type: none"> • Suparna Wedam, FDA Co-Chair, U.S. Food and Drug Administration • Alison Loren, ASCO Co-Chair, University of Pennsylvania
1:15	<p>Opening Remarks</p> <ul style="list-style-type: none"> • Julie Gralow, Chief Medical Officer, American Society of Clinical Oncology
1:20	<p>Patient Voices and the Importance of Measuring Gonadal Toxicity</p> <p>Moderator: Joyce Reinecke, Alliance for Fertility</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Dawn Ritzwoller • Tom Whiteside • Lynley Moses
1:40	<p>Session 1: Nonclinical Animal Studies</p> <p>Moderator: Stephanie Aungst, U.S. Food and Drug Administration</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Alan Hoberman, Charles River Laboratories • Christopher Bowman, Pfizer <p>Panelists:</p> <ul style="list-style-type: none"> • Shuo Xiao, Rutgers • Joseph Letourneau, University of Utah • Haleh Saber, U.S. Food and Drug Administration <p>Panel Discussion</p>
3:10	Break

3:20	<p>Session 2: Monitoring Gonadal Toxicity in Clinical Trials</p> <p>Moderator: Alison Loren, University of Pennsylvania</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Suparna Wedam, U.S. Food and Drug Administration • H. Irene Su, University of California San Diego • Robert Brannigan, Northwestern University <p>Panelists:</p> <ul style="list-style-type: none"> • Ioanna Comstock, U.S. Food and Drug Administration • Margaret Yu, Johnson & Johnson • Antonio Wolff, Johns Hopkins Medicine • Jim Cassidy, Spring Works Therapeutics <p>Panel Discussion</p>
4:50	Wrap-up and Adjourn

<p>Onco-Fertility Considerations in Drug Development</p> <p>An FDA-ASCO Virtual Workshop</p> <p>October 1 and 8, 2024</p>	
Day 2 October 8	
9:00	<p>Welcome to the Workshop and Recap of Day 1</p> <ul style="list-style-type: none"> • Suparna Wedam, FDA Co-Chair, U.S. Food and Drug Administration • Alison Loren, ASCO Co-Chair, University of Pennsylvania

<p>9:05</p>	<p>Session 3: Oncofertility</p> <p>Co-Moderators:</p> <ul style="list-style-type: none"> • Joyce Reinecke, Alliance for Fertility • Ioanna Comstock, U.S. Food and Drug Administration <p>Speakers:</p> <ul style="list-style-type: none"> • Kara Goldman, Northwestern • Lisa Campo-Engelstein, The University of Texas Medical Branch at Galveston • Ann Partridge, Dana Faber Cancer Institute <p>Panelists:</p> <ul style="list-style-type: none"> • Sukhkamal Campbell, The University of Alabama at Birmingham • Julie Wolfson, The University of Alabama at Birmingham • Laleh Amiri Kordestani, U.S. Food and Drug Administration • Michael Scherer, Worth the Wait • Katie McKnight, Bay Area Young Survivors
<p>10:35</p>	<p>Break</p>
<p>11:00</p>	<p>Session 4: The Path Forward</p> <p>Moderator and Short Recap of Workshop Sessions 1-3: Michael Barbato, U.S. Food and Drug Administration</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Stephanie Aungst, U.S. Food and Drug Administration • Alison Loren, University of Pennsylvania • Ioanna Comstock, U.S. Food and Drug Administration • Erika Hamilton, Sarah Cannon Research Institute • Natalie Kirilichin, patient advocate <p>Panel Discussion</p>
<p>12:15</p>	<p>Wrap-up and Adjourn</p>