

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
1:10	<p>Opening Remarks</p> <ul style="list-style-type: none"> • Paul Kluetz, Deputy Director, Oncology Center of Excellence, U.S. Food and Drug Administration • Julie Galow, 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

<p>1:40</p>	<p>Session 1: Nonclinical Assessments of Reproductive Toxicity</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 University • Joseph Letourneau, University of Utah • Haleh Saber, U.S. Food and Drug Administration <p>Panel Discussion</p>
<p>3:10</p>	<p>Break</p>
<p>3:20</p>	<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"> • H. Irene Su, University of California San Diego • Suparna Wedam, U.S. Food and Drug Administration • Robert Brannigan, Northwestern University <p>Panelists:</p> <ul style="list-style-type: none"> • Ioanna Comstock, U.S. Food and Drug Administration • Antonio Wolff, Johns Hopkins Medicine • Margaret Yu, Johnson & Johnson • Jim Cassidy, Spring Works Therapeutics • Nick Howe, Patient Advocate <p>Panel Discussion</p>
<p>4:50</p>	<p>Wrap-up and Adjourn</p>

Onco-Fertility Considerations in Drug Development

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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
9:05	<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"> • Lisa Campo-Engelstein, The University of Texas Medical Branch at Galveston • Kara Goldman, Northwestern • Ann Partridge, Dana Farber 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 • Michael Scherer, Worth the Wait • Katie McKnight, Bay Area Young Survivors • Laleh Amiri Kordestani, U.S. Food and Drug Administration
10:35	Break

10:45	Session 4: The Path Forward Moderator and Short Recap of Workshop Sessions 1-3: Michael Barbato, U.S. Food and Drug Administration Panelists: <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 Panel Discussion
12:15	Wrap-up and Adjourn