

Measuring Toxicity in Reproductive Organs During Oncology Drug Development

An FDA-ASCO Virtual Workshop
October 1 & 8, 2024

Biographies – Day 2

Welcome to Workshop & Day 1 Recap



Suparna Wedam, MD (Workshop Co-Chair)
Medical Oncologist, Office of Oncologic Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Suparna Wedam is a Clinical Reviewer at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Oncologic Drugs. Dr. Wedam graduated magna cum laude from Northwestern University with a B.A. in economics and then earned her medical degree from Georgetown University with election to the Alpha Omega Alpha Honor Society. She completed her internal medicine residency at Georgetown University Medical Center, where she was also a chief medical resident. Subsequently, she completed her medical oncology and hematology fellowship at the National Cancer Institute (NCI) in Bethesda, Maryland. Dr. Wedam serves as a Breast Cancer Scientific Liaison in which she routinely engages with patient advocates and the scientific community. Dr. Wedam has served on the ASCO Scientific Committee Symptoms/Supportive Care and more recently was part of the ASCO Working Group that published a statement on measuring ovarian toxicity in clinical trials. As a reviewer on the breast/gyn malignancies team, Dr. Wedam has been involved with the review of multiple drug applications and presentations at oncologic drug advisory committees. In addition, Dr. Wedam has been integral to the publication of several FDA guidance and has published in peer reviewed journals. She has been on the planning committee for the FDA/ASCO Fellows Day Workshop since its inception in 2014 and routinely lectures fellows at the NIH and Walter Reed. Dr. Wedam remains clinically active, treating breast cancer patients at Walter Reed National Military Medical Center in Bethesda, Maryland.



Alison Loren, MD, MSCE (Workshop Co-Chair)
Chief, Division of Hematology Oncology & Professor of Medicine, Perelman School of Medicine at the University of Pennsylvania
Director of Blood & Marrow Transplant, Cell Therapy & Transplant Program, Abramson Cancer Center

Dr. Alison Loren is Chief of Hematology/Oncology and Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania. She is also the Director of Blood & Marrow Transplant in the Cell Therapy & Transplant Program at the Abramson Cancer Center.

Dr. Loren specializes in hematologic malignancies and hematopoietic cell transplantation (HCT). Her clinical and research interests focus on outcomes in HCT, fertility preservation and pregnancy, and long-term survivorship. She has formal training in clinical epidemiology, biostatistics, and clinical trial design and implementation, having earned a Master's degree during her clinical fellowship in hematology/oncology.

Dr. Loren has extensive experience in collaborative clinical research. She has served as At-Large Member of the Center for International Blood & Marrow Transplant Registry's (CIBMTR) Advisory Board, Chair of the Fertility Working Group of the Late Effects Committee for the CIBMTR, Program Committee Member of the inaugural ASCO/ACP/AAFP Cancer Survivorship Symposium, and co-Chair of the CIBMTR's Regimen-Related Toxicity Working Committee. She was the Co-Chair of the American Society of Hematology (ASH) Education Program for the 2021 annual meeting and serves as ASH Councilor (2019-2023). She has co-chaired ASCO's Fertility Preservation Guideline committee and serves as Chair of the NCCN's Hematopoietic Cell Transplant Guideline committee. In addition, she is nationally recognized for leadership in education and faculty development, having served as Hematology/Oncology Fellowship Program Director at the University of Pennsylvania from 2007-2016, Vice Chair for Faculty Development in the Department of Medicine at Penn, and currently co-chairs ASH's Mentorship working group.

Dr. Loren earned her A.B from Harvard University (Biology), her M.D. from Washington University, and her M.S.C.E. from the University of Pennsylvania (Clinical Epidemiology).

Session 3: Oncofertility



Joyce Reinecke, JD (Co-Moderator)
Executive Director, Alliance for Fertility Preservation

Joyce is the Executive Director of the Alliance for Fertility Preservation, a national nonprofit organization focused on all aspects of fertility preservation for cancer patients. Prior to joining the AFP, Joyce was a Cancer & Fertility Advisor for the LIVESTRONG Foundation, and the Vice President of Programs for Fertile Hope.

She is a recognized leader in the field of fertility preservation who has been a featured speaker at numerous professional conferences, including ASCO, ASRM, ONS, the Oncofertility Consortium Conference, as well as serving as guest faculty for health policy graduate courses at UCSD and Northwestern. She is a co-author of the 2018 update of ASCO's fertility guidelines, and several other publications.

Joyce is a long-term survivor of leiomyosarcoma who opted for embryo freezing and surrogacy to create her family. Her personal oncofertility journey informs her professional focus and her commitment as a patient advocate. Prior to her work at Fertile Hope, Joyce was a trademark attorney in Seattle, WA. She has a law degree from Fordham University, and a B.A. from Occidental College. Joyce currently lives in Lafayette, CA with her husband, John, and their twin daughters, Alexandra and Olivia.



Ioanna Comstock, MD (Co-Moderator)
Medical Officer, Division of Urology, Obstetrics and Gynecology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Ioanna Comstock graduated with a B.S. in Biology from Boston College. She then earned her medical degree from Rosalind Franklin University/The Chicago Medical School. Ioanna completed her residency in Obstetrics and Gynecology at the George Washington University and later attended Stanford University for her fellowship in Reproductive Endocrinology and Infertility.

Upon completion of her fellowship, Ioanna joined the academic faculty at the George Washington University Fertility and IVF Clinic. During that time, she served as a specialist and consultant within the Department of OB/GYN to appropriately manage patients with a variety of reproductive endocrine disorders and infertility. She has published several papers in peer-reviewed journals and continues to serve as a peer reviewer for research papers submitted to world renowned journals such as Human Reproduction and Fertility and Sterility because of her research experience. Ioanna joined the Agency in September 2019 and has made significant contributions to the Division of Urology, Obstetrics and Gynecology. Given her experience with fertility preservation in female cancer patients, she has been able to assist the Oncology division with the review of clinical protocols and the development of FDA

guidance for industry regarding the enrollment of premenopausal females in cancer treatment trials and the appropriate monitoring of potential ovarian toxicity effects of anti-cancer drugs.



Lisa Campo-Engelstein, PhD
Director, Institute of Bioethics and Health Humanities
Chair, Department of Bioethics and Health Humanities
Harris L. Kempner Chair in the Humanities in Medicine Professor
University of Texas Medical Branch

Lisa Campo-Engelstein is the Director of the Institute for Bioethics and Health Humanities, the Chair of the Department of Bioethics and Health Humanities, and the Harris L. Kempner Chair in the Humanities in Medicine Professor at the University of Texas Medical Branch. She is an Elected Board Member for the International Network on Feminist Approaches to Bioethics and the American Society for Bioethics and Humanities Board. She also serves on the Advisory Board for the Male Contraception Initiative and Alliance for Fertility Preservation.

Trained in philosophy, she approaches topics in medicine from a feminist and queer perspective. She specializes in reproductive ethics, especially assisted reproductive technologies, abortion, fertility preservation, male contraception, and queer reproduction. She has been published in leading journals in medicine, science, bioethics, and feminist theory, including the *Journal of Clinical Oncology*, *Science*, the *Hastings Center Report*, and *Hypatia*. Additionally, she is the coeditor of four books— *Seminal: On Sperm, Health, and Politics* (2025); *Reproductive Ethics: New Ideas and Innovations*; *Reproductive Ethics: New Challenges and Conversations* (2017); and *Oncofertility: Ethical, Legal, Social, and Medical Perspectives* (2010).

Dr. Campo-Engelstein has been interviewed by premier national and international news organizations including National Public Radio, *The New Yorker*, the Canadian Broadcasting Corporation, and the British Broadcasting Corporation. The BBC recognized her research as engendering a better future for women, naming her as one of the 100 “inspiring and influential” Women of 2019.



Kara Goldman, MD
Associate Professor of Obstetrics and Gynecology
Associate Program Director, Fellowship in Reproductive Endocrinology and Infertility
Northwestern University

Kara Goldman, MD is an Associate Professor of Obstetrics and Gynecology and Associate Program director of the fellowship in Reproductive Endocrinology and Infertility at Northwestern University, where she also serves as Director of Fertility Preservation. Her clinical work focuses on the prevention and treatment of infertility and the preservation of fertility in patients facing gonadotoxic treatment.

Her translational work focuses on mechanisms of physiologic and iatrogenic ovarian aging, with a specific interest in the role of mTOR signaling in iatrogenic and physiologic ovarian aging as a target for pharmacologic fertoprotection. Her work has been twice awarded the Scientific Program Prize Paper award as well as the Fertility Preservation prize paper award by the American Society for Reproductive Medicine (ASRM). Her work has been recognized and funded by the Friends of Prentice, the Foundation for Women’s Wellness, and the ASRM Research Institute, and she currently serves as a consultant to NIH-funded work aiming to increase access to fertility preservation care in young cancer survivors.

Dr. Goldman plays an active national and international role in reproductive medicine, serving on the editorial board of *Fertility and Sterility* and the *Journal of Assisted Reproduction and Genetics*, chairing the ASRM Fertility Preservation special interest group, and serving on the executive board of the Oncofertility Consortium. She is an advocate for

state-level and federal passage of fertility preservation legislation and serves on the Medical Advisory Board of Team Maggie's Dream to improve access to fertility preservation care.



Ann Partridge, MD
Vice Chair, Department of Medical Oncology
Director, Adult Survivorship Program
Eric P. Winer, MD Chair in Breast Cancer Research
Dana-Farber Cancer Institute
Professor, Harvard Medical School

Dr. Partridge is vice chair of the Department of Medical Oncology at Dana-Farber Cancer Institute, where she also serves as director of the Adult Survivorship Program and co-founder and director of the Program for Young Adults with Breast Cancer. A professor at Harvard Medical School, Dr. Partridge holds the Eric P. Winer, MD Chair in Breast Cancer Research at Dana-Farber. She is dedicated to caring for patients with breast cancer and conducts clinical research focused on improving cancer care and outcomes with a particular focus on young adults with breast cancer. Dr. Partridge serves on the Board of Directors of the American Society of Clinical Oncology (ASCO) and co-chairs the National Cancer Institute (NCI) Alliance for Clinical Trials in Oncology Breast Committee and serves on the NCI Breast Cancer Steering Committee. She is also a Chief Scientific Advisor for Susan G. Komen and an American Cancer Society Clinical Research Professor, and her research has been supported by the NCI, Breast Cancer Research Foundation (BCRF), Conquer Cancer, the American Cancer Society, and Susan G. Komen. Dr. Partridge has received a Champions of Change award from the U.S. White House, the American Association for Clinical Research (AACR) Outstanding Investigator Award for Breast Cancer, the ASCO Ellen L. Stovall Award for Advancement of Cancer Survivorship Care, and the ESMO Award from the European Society of Medical Oncology for her commitment and groundbreaking work advancing the field of breast cancer.

Session 3 Panelists



Sukhkamal Campbell, MD
Director, Fertility Preservation Services, Department of Reproductive Endocrinology and Infertility
University of Alabama at Birmingham

Sukhkamal Campbell completed her undergraduate training with BS and BA degrees in biology and philosophy respectively. She then completed medical school and residency training in Obstetrics and Gynecology at the University of Alabama at Birmingham. She then completed fellowship in Reproductive Endocrinology and Infertility as well as a Masters in Clinical Science (MSCI) at Baylor College of Medicine Texas Children's Hospital in Houston, TX before returning to UAB as a faculty member in fall of 2020. Her specific focus is fertility preservation and oncofertility and she serves as the Director of Fertility Preservation Services in the Department of Reproductive Endocrinology and Infertility at UAB. Upon return to UAB in 2020, Dr. Campbell worked with colleague, Dr. Julie Wolfson, in the department of Pediatric Hematology Oncology to reinstate the UAB Fertility Preservation program in formal fashion to facilitate rapid consultations from local and regional oncology providers and to provide fertility preservation counseling and procedures for patients undergoing gonadotoxic therapies. Sukhkamal Campbell's other niche is resident and medical school education and training. She designed the REI didactics curriculum for UAB Ob/Gyn residents rotating through the rotation and also serves as a faculty lecturer and small group leader at the UAB Heersink School of Medicine through the Reproductive Module. Additionally, she was chosen to be an ABOG Faculty Examiner for Ob/Gyn General Oral Board Examinations (Certifying exam) and serves on the UAB Heersink School of Medicine Admissions Committee for incoming medical students. Outside of work, Dr. Campbell enjoys watching her boys play baseball and soccer and spending time outdoors with her family.



Julie Wolfson, MD, MSHS
Associate Professor, Department of Pediatrics
Pediatric Hematology-Oncology
Institute for Cancer Outcomes and Survivorship
Director, Adolescent and Young Adult (AYA) Oncology & Oncofertility Program
University of Alabama at Birmingham

Dr. Wolfson is a pediatric hematologist-oncologist and health services researcher. She is Associate Professor of Pediatric Hematology-Oncology and a member of the Institute of Cancer Outcomes and Survivorship at the University of Alabama at Birmingham (UAB). Her research program focuses on healthcare inequities, with particular attention to outcome disparities among adolescents and young adults (AYAs) with cancer. Her work has examined barriers to cancer care and the impact of treatment site and other aspects of cancer care delivery on relapse and survival among AYA cancer patients. In particular, she is examining the impact of patient factors such as adherence to oral chemotherapy (Study Chair, A041501-HO) and healthcare delivery (Study Chair, ACCL16N1CD) on these outcomes (both domains: R01CA248439). Along these lines, she also serves AYA patients across UAB pediatric and adult oncology as the founding Director of the UAB-COA-O'Neal AYA Oncology and Oncofertility Program. The AYA Program strategy aims to increase the rates of fertility preservation, clinical trial enrollment, psychosocial support, and physician/staff collaboration for AYAs treated across pediatric and adult oncology at UAB. She and her collaborators have a particular focus on increasing rates of fertility preservation and understanding the processes in order to enhance access. Together with Emily Johnston, MD, MS, she co-leads the Pediatric Oncology COVID-19 Case Report (POCC), the largest US registry of children with cancer and COVID-19 infections, representing >50% of US pediatric cancer sites. After an undergraduate degree in English from Harvard, she completed medical school at the University of Florida, pediatrics residency at Massachusetts General Hospital, and fellowship training at Children's Hospital Los Angeles during which she completed additional research training (MSHS) in health services research at the UCLA School of Public Health.



Michael Scherer
Patient Advocate
Co-Founder, Worth the Wait

Mike Scherer is a cancer survivor, co-founder and chief visionary of oncofertility charity Worth the Wait. He is passionate about helping other young adult cancer survivors lead meaningful lives in survivorship. He has shared his perspective with clinical and industry audiences nationally through speaking engagements, articles and podcasts. When he's not advocating for cancer awareness, he enjoys spending time with his family and cycling. Mike is also a managing partner of Summit Financial Strategies, an investment management firm.



Katie McKnight
Patient Advocate
Bay Area Young Survivors

Katie McKnight was 29 the first time she had an abnormal breast MRI. She had undergone regular breast and ovarian cancer screenings every 6 months since age 24 due to testing positive for a germline BRCA1 mutation. Katie was diagnosed with stage 2b, grade 3 triple negative invasive ductal carcinoma, at age 30.

After her diagnosis in September 2020, Katie underwent embryo cryopreservation (thanks to Senate Bill 600— a California law requiring insurance companies to cover fertility preservation ahead of lifesaving treatment with the potential to cause iatrogenic infertility), 5 months of chemotherapy, a double mastectomy with under-the-muscle reconstruction, 6 months of oral chemotherapy (Xeloda), and 4 additional breast reconstruction surgeries.

Katie is an Executive Board member of Bay Area Young Survivors, an all-volunteer, survivor-led nonprofit that supports breast cancer patients diagnosed under age 45 living in the Bay Area of California. She also volunteers with the Alliance for Fertility Preservation to advocate for and help expand young cancer patients' rights around fertility preservation and infertility treatment after a cancer diagnosis. Outside of advocating for and supporting young cancer survivors, Katie works as a Senior Design Manager and Environmental Scientist at the San Francisco Estuary Institute. She lives in Richmond, CA, with her partner Nate.



Laleh Amiri -Kordestani, MD
Medical Oncologist
Division Director, Office of Oncologic Diseases, Division of Oncology 1
Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Dr. Amiri-Kordestani is the division director of the Division of Oncology 1 (DO1) in the Office of Oncologic Diseases in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). Dr. Amiri-Kordestani earned her medical degree from the University of Tehran Medical Sciences. She completed a residency in internal medicine at the Georgetown University/Washington Hospital Center, followed by a fellowship in hematology and oncology at The National Cancer Institute (NCI).

Session 4: The Path Forward



Michael Barbato, MD (Moderator)
Medical Officer, Office of Oncologic Diseases, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Michael Barbato is a pediatric oncologist with expertise in molecularly and epigenetically driven rare solid tumors. He completed his education in pediatric hematology and oncology within the joint program between the Johns Hopkins University and the National Institutes of Health. He is currently a physician reviewer at CDER in the division of oncology 2, focusing on the safety and efficacy of trials related to pediatric rare tumors. He is also an attending physician working in the rare tumor clinic in the pediatric oncology branch at the NIH. At FDA, he also serves as the Scientific Liaison for oncofertility.

Session 4 Panelists



Stephanie Aungst, PhD (Session 1 Moderator)
Senior Toxicologist, Division of Hematology Oncology Toxicology, Office of Oncologic Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Stephanie Aungst is a Senior Toxicologist in the Division of Hematology Oncology Toxicology (DHOT), in the Office of Oncologic Diseases (OOD), in CDER. Dr. Aungst provides pharmacology and toxicology assessments of oncology drug products, including small molecules, biologics, fusion proteins, and drug-device combinations for clinical trials and marketing applications. She has 10 years of experience in drug development review of oncology drug products at the FDA. Dr. Aungst received her PhD in Neuroscience from the University of Maryland, Baltimore, and then went on to do a postdoctoral fellowship at Shock, Trauma, and Anesthesiology Research Center at the University of Maryland Medical Center.



Alison Loren, MD, MSCE (Workshop Co-Chair)
Chief, Division of Hematology Oncology & Professor of Medicine, Perelman School of Medicine at the University of Pennsylvania
Director of Blood & Marrow Transplant, Cell Therapy & Transplant Program, Abramson Cancer Center

See above entry



Ioanna Comstock, MD (Session 3 Co-Moderator)
Medical Officer, Division of Urology, Obstetrics and Gynecology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

See above entry



Erika Hamilton, MD
Director, Breast Cancer Research Program
Sarah Cannon Research Institute

Dr. Hamilton received her undergraduate degree from Washington and Lee University in Virginia and received a NCAA Postgraduate Scholarship. She then completed her medical degree and residency from University of North Carolina in Chapel Hill and fellowship training in oncology at Duke University. She joined Sarah Cannon Research Institute as investigator in drug development for women's cancers in 2013. Since 2015 she has served as the Director of the Breast Cancer Research Program. She sees patients facing breast cancer from standard of care to phase II/III to phase I drug development.

Dr. Hamilton was named to the Women to Watch Class of 2021 for Nashville Medical News. She was selected for ASCO's Leadership Development Class for 2021-2022, the past Chair of ASCO's Scientific Committee for Metastatic Breast Cancer for 2019-2020, and currently serves on ASCO's Cancer Research Committee, and will be the 2025 ASCO Annual Meeting Scientific Chair. She also is the 2023-2025 Scientific Committee Co-Chair of the ESMO Breast Cancer Meeting and is on the Scientific Committee for AACR for 2023. She serves as an Associate Editor for Clinical Breast Cancer.



Natalie Kirilichin, MD, MPH
Patient Advocate
Assistant Professor, George Washington University, Department of Emergency Medicine

Natalie Kirilichin, MD, MPH is a physician educator, health policy expert, and patient advocate. She is a board-certified emergency medicine doctor and assistant professor at the George Washington University (GWU) Department of Emergency Medicine. As faculty, she works at GWU and The Walter Reed National Military Medical Center clinically caring for patients and training medical students and residents. Her education leadership roles include directing the [GWU MFA Health Policy and Advocacy Fellowship](#), the award-winning [Residency Fellowship in Health Policy](#), and the [Graduate Medical Education Clinical Public Health Tracks Program](#) at the School of Medicine.

Dr. Kirilichin's policy expertise stems from practical and lived experience. As a health policy fellow with [The U.S. Senate Committee on Health, Education, Labor and Pensions \(HELP\)](#), her work supported transformative behavioral health legislation. She also served as a medical advisor for [National Safety Council](#), a nonprofit that eliminates preventable deaths through leadership, research, education and advocacy. She has held various leadership positions within the [American College of Emergency Physicians \(ACEP\)](#) including Past President of its DC Chapter. Finally, Dr. Kirilichin serves on the Advisory Committee for [DC Health's Prescription Drug Monitoring Program \(PDMP\)](#).

Dr. Kirilichin is also a cancer survivor and advocate with firsthand experience navigating onco-fertility challenges. She leveraged her own cancer battle to improve university-wide insurance coverage for onco-fertility services and awareness of its medical necessity.

Dr. Kirilichin received her undergraduate degree (BS, Biology) from Georgetown University, and remained at Georgetown's School of Medicine to complete her MD. She earned her MPH from the GWU Milken Institute School of Public Health. She completed her emergency medicine residency at University of Chicago Hospitals.