Measuring Toxicity in Reproductive Organs During Oncology Drug Development

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

Biographies – Day 1

Introduction to Workshop

Suparna Wedam, MD
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 guidances 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
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).

Opening Remarks

Paul G. Kluetz, MD
Deputy Director
Oncology Center of Excellence, FDA

Dr. Paul Kluetz is a medical oncologist and the Deputy Director of the Oncology Center of Excellence at the U.S. FDA. In addition to assisting in the strategic and operational oversight of the OCE, he holds an acting role overseeing the solid tumor and toxicology Divisions within the Office of Oncologic Diseases. Paul has a broad interest in trial design and endpoint selection as well as evidence modernization to expedite drug development and define clinical benefit in oncology trials. Some of his initiatives include creation of the OCE's patient-focused drug development program and expansion and direction of OCE's efforts to advance real-world evidence, decentralized trial design and digital health technology. He is also active in regulatory review of Oncology products and oversees important oncology drug labeling initiatives. Dr. Kluetz remains clinically active, caring for patients and supervising medical residents at the Georgetown University Hospital.

Julie Gralow, MD
Chief Medical Officer, American Society of Clinical Oncology

Julie R. Gralow, MD, is Chief Medical Officer for the American Society of Clinical Oncology (ASCO). She is a breast medical oncologist and Professor (emeritus) of Medical Oncology and adjunct Professor of Global Health at the University of Washington School of Medicine. Dr. Gralow is the former Executive Officer for Breast and Lung Cancer and Vice Chair of the Breast Cancer Committee for the SWOG Cancer Clinical Trials Network. She is committed to improving quality of life for patients with cancer, and is co-Founder of Team Survivor Northwest, a non-profit aimed at helping female cancer survivors improve their health through fitness and exercise, and the Women's Empowerment Cancer Advocacy Network (WE CAN) to support cancer advocacy and education in low- and middle-income countries.

Patient Voices and the Importance of Measuring Gonadal Toxicity

Joyce Reinecke, JD (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.

Dawn Ritzwoller, MPH
Cancer Survivor and Adolescent and Young Adult (AYA) Cancer Patient Navigator
Huntsman Cancer Institute

Dawn Ritzwoller is an ovarian germ-cell cancer survivor, diagnosed at the age of 13. Her early experience as a young cancer patient has shaped her dedication to improving the care and support of adolescent and young adult cancer patients, with a focus on oncofertility. Dawn earned her Master of Public Health from the Gillings School of Global Public Health at the University of North Carolina (UNC), where she contributed to AYA cancer research and developing survivorship care guidelines. She currently serves as an AYA Cancer Patient Navigator at the Huntsman Cancer Institute, advocating for fertility preservation and patient education while working to enhance survivorship care for AYA cancer patients. Dawn's work is deeply informed by her personal journey and academic training.

Tom Whiteside
Patient Advocate

Tom Whiteside is a resident of Golden, CO and a graduate of the University of Texas. At age 26 he was diagnosed with stage IV Hodgkin's lymphoma. After six rounds of high-dose chemo and 28 days of radiation therapy, he was declared "in remission" and has been healthy since. Though treatment took his fertility, thanks to foresight from his medical oncologist and access to fertility preservation, Tom now has an adorable two-year-old daughter, Rosemary, with his wife Laura. Tom is a financial planner who enjoys films, good coffee, travel and reading.

Lynley Moses, MPH
Patient Advocate
Exercise Physiologist, TIRR Memorial Hermann

Lynley Moses is an Exercise Physiologist with a Master's in Public Health, earned in March 2023. She holds multiple certifications from the American College of Sports Medicine and is dedicated to advancing her career as a Global Epidemiologist. Lynley aims to develop impactful preventive health initiatives for high-risk countries. A breast cancer survivor, her personal journey has fueled her passion for public health and wellness.

Session 1: Nonclinical Assessments of Reproductive Toxicity

Stephanie Aungst, PhD (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.

Session 1 Presenters:

Alan Hoberman, PhD, DABT, Fellow ATS
Executive Director, Global Development, Reproductive and Juvenile Toxicity
Charles River Laboratories

Dr. Hoberman has been employed by Charles River Laboratories, Preclinical Services, Pennsylvania (formerly Argus Research Laboratories, Inc.) since 1981, serving as Study Director, Director of Reproductive Toxicology and currently as Executive Director, Global Developmental, Reproductive and Juvenile Toxicology. Prior to joining Argus Research, Dr. Hoberman was the Head of Reproductive Toxicology at Hazleton Laboratories in Vienna, Virginia. He received his BS in Biology from Drexel University and was a graduate student in Anatomy at the University of Virginia before moving to Arkansas and completing a MS in Interdisciplinary Toxicology from the University of Arkansas and a Ph.D. in Toxicology from Pacific Western University.

He is a Diplomat of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences, with over 100 publications and book chapters. He is the co-editor of *"Pediatric Non-Clinical Drug Testing, Principles, Requirements, and Practices"* published in January 2012.

Dr. Hoberman has been a member of Birth Defects Research and Prevention since 1978, American College of Toxicology since 1979, Middle Atlantic Reproduction and Teratology Association since 1984 and the Reproductive and Developmental Toxicology Specialty Section of the Society of Toxicology, since 1987. He

is a Past President of each of these groups. He is also a member of the European Teratology Society since 1982, and past councilor, past president of the Arkansas Biotechnology Organization and a Board member of the Pennsylvania Society of Biomedical Research.

Christopher Bowman, PhD
Research Fellow, Drug Safety Research & Development, Safety Sciences
Pfizer

Chris has over 25 years' experience in developmental and reproductive toxicology (DART). Chris earned his PhD in 2001 from University of Florida in environmental toxicology, served as a post-doc for 2 years at CIIT in North Carolina studying toxicity of antiandrogens, spent 5 years as a study directing DART studies at WIL Research (now Charles River) and since 2008 has enjoyed serving as a nonclinical subject matter expert in DART at Pfizer. Chris has authored over 60 publications, is a diplomate of the American Board of Toxicology, past President of the Reproductive and Developmental Toxicology Specialty Section of the Society of Toxicology, former member of the ICH S5R3 expert working group, and is currently serving as the Industry Chair of the Health and Environmental Sciences Institute Technical Committee on DART, and Associate Editor of Birth Defects Research.

Session 1 Panelists:

Shuo Xiao. PhD
Associate Professor, Department of Pharmacology and Toxicology
Ernest Mario School of Pharmacy
Environmental and Occupational Health Science Institute
Rutger University

Dr. Shuo Xiao is an Associate Professor from the Department of Pharmacology and Toxicology at Rutgers University School of Pharmacy. He earned his MBBS in Preventive Medicine and MS in Toxicology from Peking University Health Science Center, followed by a PhD in Female Reproductive Biology and Toxicology from Dr. Xiaoqin Ye's lab at the University of Georgia. He completed his Postdoctoral Training in Dr. Teresa Woodruff's lab at Northwestern University. Dr. Xiao's current research is dedicated to advancing women's reproductive health, including (1) ovarian impacts of environmental contaminants and clinical drugs; (2) non-hormonal female contraception development, and (3) engineering female reproduction-on-chip. These projects are funded by NIH, DOD, NSF, and Bill & Melinda Gates Foundation. Dr. Xiao has published > 60 peer-reviewed papers in high impact journals, including Nature Communications, Environmental Health Perspectives, Biology of Reproduction, and Toxicological Sciences. Dr. Xiao now serves as the Chair of Basic Science Committee of Oncofertility Consortium, President of American Association of Chinese in Toxicology (AACT), Secretary/Treasurer of the Society of Toxicology (SOT) Reproductive and Developmental Specialty Section (RDTSS), and Toxicology Division Councilor of the American Society for Pharmacology and Experimental Therapeutics (ASPET).

Joseph Letourneau, MD
Assistant Professor, Reproductive Endocrinology and Infertility
Co-Director, Oncofertility Program
University of Utah

Dr. Letourneau is an Assistant Professor of Reproductive Endocrinology and Infertility at the University of Utah, where he serves as co-director of the University of Utah's Oncofertility Program. The University of Utah's oncofertility clinic serves as a referral center for the United States' Intermountain West Region, including cities and rural areas in Utah, Nevada, Idaho, Montana, Wyoming, Western Colorado and Northern Arizona.

Dr. Letourneau is an active clinician-researcher. He is an ASRM/NICHD CREST Scholar and a recipient of numerous grants, including the ASRM Young Investigator Grant. Dr. Letourneau has published over 70 research articles and abstracts in the field of oncofertility. He has also worked to help to ensure more universal insurance coverage for oncofertility services, including recently helping to make Utah the second state to cover oncofertility services under the state's Medicaid plan.

Haleh Saber, PhD
Acting Director, Division of Hematology Oncology Toxicology, Office of Oncologic Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Saber is the Acting Director in the Division of Hematology Oncology Toxicology (DHOT), in the Office of Oncologic Diseases (OOD), in CDER. In this role she provides leadership for day-to-day activities, participates in inter-Agency initiatives, leads and coordinates scientific research, and participates in guidance development. Dr. Saber was the lead author of several guidance documents, including *Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations*, and *Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations*. Dr. Saber has over 20 years of experience in drug development in pharmaceutical industry and at the FDA. She is recognized for her efforts in establishing acceptable approaches in first-in-human dose selection for new classes of products. Dr. Saber received her PhD in Biochemistry from Lehigh University, PA, and conducted her post-doctoral studies at Fox Chase Cancer Center, PA.

Session 2: Monitoring Gonadal Toxicity in Clinical Trials

Alison Loren, MD, MSCE (Moderator)
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

Session 2 Presenters:

H. Irene Su, MD, MSCE
Professor of Obstetrics, Gynecology and Reproductive Science, Division of Reproductive Endocrinology and Infertility
University of California, San Diego

Irene Su is a Professor of Obstetrics, Gynecology and Reproductive Science in the Division of Reproductive Endocrinology and Infertility at the University of California, San Diego, where she currently serves as program director of the fellowship program in reproductive endocrinology and infertility and co-director of UC San Diego's new Center for Ob/Gyn Research Innovation. She completed her medical degree at Albert Einstein College of Medicine, followed by residency training on obstetrics and gynecology, fellowship in reproductive endocrinology and infertility, and a Master's of Science in Clinical Epidemiology at the University of Pennsylvania. As a physician scientist, Dr. Su conducts research focused on estimating reproductive risks and intervening on reproductive health of young cancer patients. Dr. Su directs the clinical fertility preservation program at UC San Diego. Her clinical care of cancer survivors with reproductive health needs informs her group's clinical, translational and health policy research.

Suparna Wedam, MD
Medical Oncologist, Office of Oncologic Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

See above entry

Robert Brannigan, MD
Professor and Vice Chair of Clinical Urology, Department of Urology
Northwestern University, Feinberg School of Medicine

Robert E. Brannigan, MD is a Professor and Vice Chair of Clinical Urology in the Department of Urology at Northwestern University, Feinberg School of Medicine with a clinical focus on male reproductive medicine and surgery. He obtained his undergraduate and medical degrees from Northwestern University. After completing residency training in Urology at Northwestern, he completed a fellowship in Male Reproductive Medicine and Surgery at Baylor College of Medicine. Dr. Brannigan returned to join the faculty at Northwestern, where he is Head of the Division of Male Reproductive Surgery & Men's Health and Medical Director of the Department of Urology's Clinic. Dr. Brannigan is Director of the Andrology Fellowship at Northwestern. His research interest is in fertility preservation, with a focus on optimizing the delivery of this clinical care to adolescents and adults with an oncologic diagnosis. At Northwestern, he also serves as the Assistant Director of Student Affairs for the Feinberg School of Medicine, and in this role, he is extensively involved in medical student career advising and mentorship, as well as oversight of the medical school's learning environment.

Dr. Brannigan has served in the leadership of several national organizations and societies. He is a Past President of the Society for the Study of Male Reproduction (SSMR) and the Society for Male Reproduction and Urology (SMRU), and he is currently the Vice President of the American Society for Reproductive Medicine (ASRM). He is a former Assistant Editor for *The Journal of Urology* and Associate Editor for *Fertility and Sterility,* and he is currently on the Editorial Board of the *AUA Update Series*. He serves as a senior

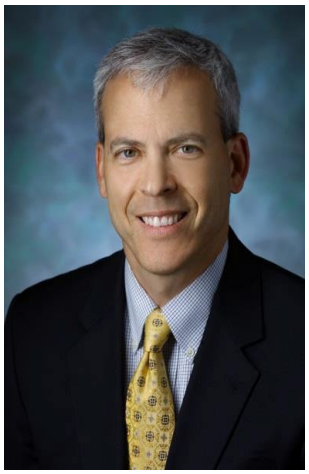
consultant on the American Board of Urology Examination Committee, and in 2021, he was elected to the American Association of Genitourinary Surgeons (AAGUS).

Session 2 Panelists:

Ioanna Comstock, MD
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 guidances 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.



Antonio Wolff, MD, FACP, FASCO
Professor of Oncology, The Johns Hopkins University School of Medicine Interim Director, Breast & Gyn Malignancies Group
The Johns Hopkins University Sidney Kimmel Comprehensive Cancer Center

Dr. Antonio Wolff is a Professor of Oncology at Johns Hopkins University and Interim Director, Breast & Gyn Malignancies Group at the Johns Hopkins Kimmel Comprehensive Cancer Center. He is a practicing breast cancer medical oncologist and translational investigator with expertise in therapeutic clinical trials, biomarker development and implementation, survivorship, clinical practice guidelines, and quality initiatives. He is past member of American Society of Clinical Oncology's Quality of Care Committee, past Chair of ASCO's Health Services Research Committee, and a member of the National Comprehensive Cancer Network (NCCN) Guideline Steering Committee. He is Panel Co-Chair and a lead author/senior author of the ASCO/College of American Pathology clinical practice guidelines on HER2 and hormone receptor testing in breast cancer. He has experience in collaborative, multidisciplinary national and international breast cancer clinical trials and on the integration of research findings into clinical practice. He co-founded the Translational Breast Cancer Research Consortium (www.tbcrc.org) and serves as its Chief Operating Officer. In 2009 he received a National Cancer Institute Cancer Clinical Investigator Team Leadership Award. He is immediate past Chair of the ECOG-ACRIN Breast Cancer Committee and now serves as Co-Chair of the NCI's Breast Cancer Steering Committee. He is a Fellow of ASCO and was named a Susan G. Komen Scholar (2010-2021 and again as of 2023). He was identified in 2017 by Clarivate Analytics (Thomson Reuters) as one of the world's

most highly cited researchers (top 1% in clinical medicine). Dr. Wolff served as Associate Editor of Journal of Clinical Oncology (2012-2022). At Johns Hopkins, he is a member of the Professorial Promotions Committee of the School of Medicine, and was inducted in 2018 in the JHU Miller Coulson Academy of Clinical Excellence. As part of the 125th anniversary celebration of the JHU School of Medicine, he was recognized as one of 125 Living the Hopkins Mission Honorees, who were selected for their outstanding dedication to the institution's core values of excellence and discovery, leadership and integrity, diversity and inclusion, and respect and collegiality.

Margaret Yu, MD
Vice President, Oncology
Johnson&Johnson Innovation Medicine

Margaret K. Yu, MD is Vice President in the Oncology Therapeutic Area at J&J. She is a medical oncologist with 17 years of oncology drug development experience in the biotech/pharmaceutical industry.

Margaret Yu joined Janssen in 2010 as a study responsible physician; showing strong leadership skills, she was promoted to Vice President and eventually led the clinical development programs in prostate cancer. In her roles, she built and led the team to execute a broad development strategy, resulting in acceleration of key development milestones and delivery of high-quality data to inform decision making. She has successfully built and managed several drug development programs which led the team to the first regulatory submission and US approval in patients with non-metastatic castration resistant prostate cancer development. Between 2019-2024, Margaret led the Prostate Disease Area Stronghold at J&J and is now responsible for oncology asset strategy.

Prior to joining J&J, Margaret worked as the Assistant Professor, Hematology and Medical Oncology Division in the Internal Medicine department at the University of Utah. She joined the pharmaceutical industry in 2007 as the Director of Clinical Research at Myriad Pharmaceuticals, Inc. (Myrexis, Inc.) where she provided clinical leadership and medical monitoring oversight for all clinical trials in oncology. She led the development for two solid tumor malignancies.

Margaret completed her residency in Internal Medicine and Medical Oncology and Hematology fellowship at the University of Utah School of Medicine. She has authored numerous publications.

Margaret combined her passion for oncology and her love of the outdoors by participating, along with several co-workers, in The CureSearch Ultimate Hike, conquering 20+ miles along the Pacific Crest Trail in a single day. This trek is a stride towards a vital cause; funding critical research to discover more cures and safer treatments for children battling cancer. The Hike was such a great success it has continued with the J&J employees the past 4 years.

Jim Cassidy, MD, PhD
Chief Medical Officer, SpringWorks Therapeutics

Dr. James (Jim) Cassidy joined SpringWorks in 2021. He has over 30 years of experience in oncology as an academic physician-scientist and a drug development leader in both biotechnology and pharmaceutical companies, with experience spanning from early-stage research to translational and clinical development to post-marketing medical affairs strategy and lifecycle management. Previously, Jim was Vice President of Oncology Strategic Program Direction at Regeneron Pharmaceuticals. Prior to Regeneron, Jim was Corporate Vice President of Translational Development at Celgene, where he oversaw translational science efforts for the company's entire portfolio of programs addressing both hematological malignancies and solid tumors. Before Celgene, he was Vice President of Oncology at Bristol-Myers Squibb, where he was responsible for all oncology assets from development candidate nomination through clinical proof-of-concept studies, including biomarkers and translational research, and was closely involved with late-stage development, commercial, and business development efforts as well. Prior to Bristol-Myers Squibb, Jim held several roles of increasing responsibility at Hoffmann La-Roche, including Global Head of Translational Research for Oncology and Acting Head of the Oncology Therapy Area. Before joining Roche, he had been a leading academic physician-scientist, most recently having served as Professor of Oncology, Head of the Department of Cancer Research and Head of the Division of Cancer Sciences and Molecular Pathology at the University of Glasgow in Scotland. Jim received his medical degree and doctorate from the University of Glasgow.

Nick Howe
Patient Advocate

My name is Nick Howe I am a professional firefighter here in Omaha. In 2016, I began experiencing a variety of severe health issues, including liver and kidney failure and the loss of roughly 45 pounds within the span of a couple of months. I was eventually diagnosed with Diffuse Large B-Cell Non-Hodgkin Lymphoma. I went through multiple rounds of chemo, immunotherapy and an autologous stem-cell transplant, all of which failed. Then, as a last-ditch effort to save my life, we decided to undergo a highly experimental clinical trial known as CAR T-cell therapy. It was successful. I was number 6 of the first 10 patients to receive this particular therapy out of Seattle. I have been in remission for close to 7 years now.

Our story doesn't end there. In May of 2022, everything started spiraling downhill again. I had a cough I couldn't shake and over the next few weeks, it would get worse. I was taken to the hospital by ambulance and immediately put on an RVAD machine due to myocarditis and would eventually need a heart transplant which I received only a few weeks later. Weeks later, I was back in the hospital. My new heart was now failing due to the same virus. This time I was placed on ECMO for about 3 weeks. During that time, I had an ischemic spinal stroke which left me paralyzed from the waist down.

Through all of this— my wife and I have depended on IVF to start our family due the effects of my cancer treatments. Today, we have three amazing children, Julia age six and twin boys Miles and Levi age three. It hasn't been easy but I am thriving because I have a family to live for.