

Non-Muscle Invasive Bladder Cancer Workshop
Day 1: November 18, 2021 9:00 AM - 1:00 PM ET
Virtual

Biographies

Workshop Day 1 Opening Remarks

Elaine Chang, MD



Elaine Chang, MD is a medical oncologist at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Oncologic Diseases (FDA). She completed her hematology/oncology fellowship at Baylor College of Medicine and joined FDA in 2018.

She is serving as one of the Acting Team Leads for the Genitourinary Malignancies Team in Division of Oncology 1. Her research has focused on novel endpoints in renal, bladder, and prostate cancer. She has an interest in facilitating multi-stakeholder discussions on clinical trial design and rational drug development strategies that address unmet needs.

Session 1: BCG Shortage

Seth Lerner, MD (Presenter)



Seth P. Lerner, MD, is Professor of Urology and holds the Beth and Dave Swalm Chair in Urologic Oncology and is Vice-chair for Faculty Affairs in the Scott Department of Urology, Baylor College of Medicine. He is Director of Urologic Oncology and the Multidisciplinary Bladder Cancer Program. He earned his medical degree from Baylor College of Medicine, completed a surgical internship at Virginia Mason Hospital in Seattle, and returned to Baylor for his residency training. He completed a two-year fellowship at the University of Southern California in urologic oncology and reconstructive surgery under Peter Jones and Don Skinner before returning to join the full-time Baylor faculty in 1992.

His clinical practice, education, and research activities are devoted to urologic oncology and particularly lower and upper tract urothelial cancer. Dr. Lerner is author of 220 peer-reviewed articles, and co-editor of a comprehensive Textbook of Bladder Cancer. He is the founding co-editor-in-chief of the Bladder Cancer journal. He established and directs the multi-disciplinary Bladder Cancer Research Program at Baylor and his research interests include use of selective estrogen receptor modulators for treatment of bladder cancer, gene therapy, integrated proteogenomic analysis of bladder and upper urinary tract cancers, and outcomes of radical cystectomy and pelvic lymphadenectomy.

He has 29 years of experience as a clinical investigator for both NCI and industry funded clinical trials. He is the PI of the ongoing SWOG NCI Phase III trial comparing extended vs. standard pelvic

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lymphadenectomy at time of radical cystectomy. He is active in the leadership of several national bladder cancer research enterprises including chair of the Local Bladder Cancer committee of SWOG, founding and former co-chair of the NCI Bladder Cancer Task Force and current co-chair of the NCI CTEP Genitourinary Steering Committee, and he co-chaired the Analysis Working Group of The Cancer Genome Atlas Project for muscle invasive bladder cancer for. He was recently appointed to a 4-year term to the NCI Clinical Trials and Translational Research Advisory Committee. He is very active in the Bladder Cancer Advocacy Network (BCAN) as a member of the Board of Directors, past chair of the Bladder Cancer Think Tank and co-chair of the management committee of the Bladder Cancer Research Network. Dr. Lerner is an active member of the prestigious American Association of Genitourinary Surgeons and is listed routinely among “America’s Top Doctors” and “Best Doctors in America.

Robert Svatek, MD (Presenter)



Rob Svatek is Professor and Chair at the Department of Urology, UT Health San Antonio. He completed his urology residency training at the University of Texas Southwestern Medical Center in Dallas and urologic oncology training at MD Anderson Cancer Center. He also earned his Master of Science in Clinical Research Investigation at the UT Health Science Center at Houston, Center for Clinical Research and Evidence-Based Medicine. At the conclusion of his fellowship, he joined the department of urology at UT Health San Antonio.

Dr. Svatek’s clinical practice is devoted to the care of patients suffering from bladder cancer. The urology department at UT Health San Antonio serves a large referral base that includes the South and Southwest borders of Texas and he is proud to lead a group of exceptional urologic clinicians and scientists.

Dr. Svatek is passionate about clinical trial research for bladder cancer and he runs an NIH-funded cancer immunology laboratory, which focuses on the role of innate effector cells in mediating cancer immune surveillance and cancer therapy. Dr. Svatek’s research team conduct clinical trials that interface with laboratory and bladder cancer animal models, creating synergy between these parallel research approaches. Dr. Svatek is also actively involved in the development and conduct of trials through the Southwest Oncology Cooperative Group (SWOG), one of several cooperative groups within the National Cancer Institute’s publicly funded National Clinical Trials Network.

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Chana Weinstock, MD (Moderator)



Chana Weinstock, MD is a medical oncologist and hematologist specializing in genitourinary (GU) oncology. She has been a GU oncology team leader at the U.S. Food and Drug Administration since 2017. She is a graduate of University of Toronto (with high distinction) and the Albert Einstein College of Medicine. She has practiced thoracic and genitourinary oncology at the University of Maryland Medical Center and at the Baltimore Veterans' Affairs Medical Center, where she remains on staff.

Her original oncology research has been published in journals such as the JCO, Journal of Urology, and Clinical Cancer Research, and she has presented at national meetings including ASCO, ASTRO, RSNA, SABCS, and CAMO, including oral presentations at ASCO, ASCO GU symposium, and at ASTRO workshops. She served as the track leader of ASCO's GU oncology kidney and bladder cancer educational track in 2021 and remains on the educational committee and serves on the Bladder Cancer Advocacy Network (BCAN) Annual Meeting planning committee. She has recently been involved in organizing several workshops and minisymposia on clinical trial design and endpoint definition in GU oncology.

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Peter Bross, MD



Peter Bross is acting Chief of Oncology Branch and clinical team leader in the FDA Center for Biological Evaluation and Research (CBER), Office of Tissue and Advanced Therapies (OTAT) and previously worked as a clinical reviewer in the Division of Oncology Drug Products in the Center for Drug Evaluation and Research (CDER). Over 20 years at FDA, Dr. Bross has gained expertise in the design and analysis of clinical oncology trials of cellular, tissue and gene therapies, especially cancer vaccines, combination therapies, and companion diagnostics.

As a regulatory reviewer, he has reviewed new molecular entities for marketing approvals in solid tumors and hematological malignancies, including oncolytic viruses, cellular immunotherapies, targeted kinase inhibitors, proteasome inhibitors and an antibody-drug conjugate. He has presented FDA perspectives at professional meetings and review findings at FDA advisory committee meetings, and he has authored several manuscripts. Dr. Bross is a graduate of University of Virginia Medical School and trained in Hematology and Oncology at The George Washington University. He has been at FDA since 1999.

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Max Kates, MD



Dr. Max Kates is an Assistant Professor of Urology and Oncology and Director of the Bladder Cancer Program within the Brady Urological Institute at Johns Hopkins School of Medicine. Dr. Kates has clinical expertise in all areas of urologic oncology, with a particular emphasis on the surgical management of complex prostate and bladder malignancy.

His research interests parallel his clinical practice, with a focus on evaluating novel therapies for early-stage bladder cancer and identifying predictive biomarkers of disease response. His research is funded by the American Cancer Society's Career Development Award program.

Neal Shore, MD



Dr. Neal Shore graduated both Duke University and Duke University Medical School. He completed his general surgery/urology residence at New York Hospital-Cornell Medical Center/Memorial Sloan Kettering Cancer Center.

He is the Medical Director, for the Carolina Urologic Research Center. He practices with Atlantic Urology Clinics in Myrtle Beach, South Carolina. Dr Shore has conducted more than 400 clinical trials, focusing mainly for GU Oncology indications. He is the Chief Medical Officer, Surgery/Urology, for GenesisCare,US. He has more than 250 peer reviewed publications and numerous book chapters.

He serves on the SITC Guidelines Committee for Bladder Cancer as well as the boards of the Bladder Cancer Advocacy Network and the Duke Global Health Institute. He is the Chair of the LUGPA Education Committee. He is on the editorial boards of Reviews in Urology, Urology Times, Chemotherapy Advisor, Onclive, PLOS ONE, Urology Practice, World Journal of Urology, and also serves as Editor, Everyday Urology-Oncology. He is a Fellow of the American College of Surgeons.

Karen Sachse



Karen Sachse was diagnosed 10 years ago with non-muscle invasive bladder cancer. After completion of BCG induction, her disease was found to be refractory & she moved on to further medical treatments with intravesical chemotherapy. She was finally disease free after 4 years of intermittent treatment. Karen credits the saving of her life, and her bladder, to the expertise at an NCI-designated bladder cancer center. In 2016, Karen's husband presented her with shocking news. Roger was diagnosed with muscle invasive bladder cancer. He underwent neoadjuvant chemotherapy, followed by a radical cystectomy with neobladder diversion. Unfortunately, Roger's disease metastasized to the central nervous system and he died 15 months after diagnosis.

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Karen volunteers extensively with the Bladder Cancer Advocacy Network. Here are just a few highlights. She serves as a patient advisor for the PCORI study, "Comparing Intravesical Therapy & Surgery as Treatment Options. She is a consumer reviewer for the Congressionally Directed Medical Research Program, Peer Reviewed Cancer Research. In 2019, Karen was recognized as the "BCAN volunteer of the Year".

Currently, Karen works as a Nurse Navigator for INOVA's Life with Cancer Program in Alexandria, VA where she facilitates a bladder cancer support group for patients & caregivers.

Seth Lerner, MD

(See above)

Robert Svatek, MD

(See above)

Session 2: BCG-Naïve Setting

Noah Hahn, MD (Presenter)



Dr. Hahn is a professor of Oncology and Urology at the Johns Hopkins University School of Medicine. He serves as the Director of the Medical Oncology Bladder Cancer Program and the Deputy Director of the Johns Hopkins Greenberg Bladder Cancer Institute. Dr. Hahn is an internationally recognized authority in the conduct of bladder cancer novel therapeutic clinical trials and translational investigations.

He maintains an active clinical practice and sees patients with urothelial cancers of all locations and stages including non-muscle invasive bladder cancer. Dr. Hahn's clinical and translational research interests focus on improving outcomes for patients with urothelial cancers through: 1) The development of novel epigenetic, targeted, and immunomodulatory approaches to treat and prevent urothelial cancer; 2) The credentialing of the naturally-occurring, immunocompetent canine-human tumor model as a relevant comparative oncology model optimal for the pre-clinical study of candidate human urothelial cancer biomarkers and therapeutics; and 3) The identification and validation of predictive biomarkers relevant to urothelial cancers.

In addition to his efforts at Johns Hopkins, Dr. Hahn serves as the bladder cancer chairman of the Eastern Cooperative Oncology Group - American College of Radiology Imaging Network (ECOG-ACRIN), participates on the NCI Bladder Cancer Task Force, and serves on the scientific advisory board of the Bladder Cancer Advocacy Network.

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Adnan Jaigirdar, MD (Moderator)



Adnan Jaigirdar, MD, FACS is a surgical oncologist in the Oncology Branch, Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT), in the Office of Tissues and Advanced Therapies (OTAT) at the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA). He received his B.S. (Summa Cum Laude) in Chemistry, and then his M.D. (Alpha Omega Alpha) at the University of Cincinnati. During this time, he also trained in cancer immunology focusing on tumor vaccines, at the National Cancer Institute (NCI) as a Howard Hughes Medical Institute-National Institutes of Health (HHMI-NIH) Research Scholar. He received his general surgery training at the University of California, San Francisco (UCSF), where he also was a post-doctoral research fellow at the UCSF Dept. of Surgery, Transplant Division, studying mechanisms of immune tolerance.

He completed his Surgical Oncology training at NCI. There he also conducted research in cell and immunotherapy at the Surgery Branch. Prior to joining the FDA, Dr. Jaigirdar was a practicing surgical oncologist in the U.S. Navy at the Walter Reed National Military Medical Center, Fort Belvoir, and as a clinical assistant professor of surgery at Uniformed Services University of the Health Science (USUHS). He joined the FDA in 2016 and focuses in the review of investigational biologic and combination advanced therapies involving cell and gene therapy in solid tumors.

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Erik Bloomquist, PhD



Dr. Erik Bloomquist is a mathematical statistician and team leader in the Division of Biostatistics 5, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research (CDER). He has over 10 years of experience at FDA working in the Center for Devices and Radiological Health (CDRH) and CDER. His research interests include: prediction and forecasting models for survival analysis, auditing methods for blinded independent central review, and methods to derive balanced cohorts from multi-cohort external controls.

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Jamie Brewer, MD



Jamie Brewer, MD is a medical oncologist and Acting Clinical Team Lead in the Division of Oncology 3 (DO3) in the Office of Oncologic Diseases (OOD) at the Food and Drug Administration (FDA). Dr. Brewer joined the FDA in 2018 and previously served as a clinical reviewer on the Genitourinary Cancer team. Dr. Brewer serves as the Oncology Center of Excellence (OCE) Scientific Liaison for Cancer Disparities for which she actively engages with FDA colleagues and external stakeholders to promote inclusion and representation of diverse patient populations in clinical trials.

Dr. Brewer is an active contributor to OCE initiatives such as Project Equity and Project Community. She is also a participant in multiple internal and external scientific working groups. Dr. Brewer completed her medical training at The University of Illinois at Chicago. She completed her residency and a joint fellowship in Medical Oncology and Clinical Pharmacology and Pharmacogenomics at The University of Chicago.

Michael O'Donnell, MD



O'Donnell, MD, is the Richard D Williams Professor of Urology and director of urologic oncology at the University of Iowa, Iowa City, IA. An expert in the field of bladder cancer, he is esteemed around the world for his research on bladder cancer.

Dr. O'Donnell is a graduate of the Duke University School of Medicine (Durham, NC) and the Harvard urology residency program (Boston, MA). He completed fellowships at both Harvard's Beth Israel Hospital in Boston and the Whitehead Institute of Biomedical Research at MIT in Cambridge, MA. He is a fellow of the American College of Surgeons, and a member of the American Urological Association (AUA), Society of Urologic Oncologists (SUO), American Association of Immunologists (AAI) and many others.

Dr. O'Donnell was an early adopter of Blue Light Cystoscopy with Cysview® in 2011, making him one of the most experienced users of the technology in the OR. He encourages adoption in his institution and advocates to the urology community for more widespread use.

In his research, Dr. O'Donnell focuses on the anti-cancer mechanisms of BCG and its enhancement with combination therapies. He has pioneered several new sequential combination therapies involving Adriamycin, gemcitabine, docetaxel and mitomycin for treating BCG-resistant/recurrent bladder cancers.

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Gary Steinberg, MD



Gary Steinberg, MD, Professor Department of Urology and the Perlmutter Cancer Center NYU Langone Health and Director Goldstein Urology Program in Bladder Cancer, specializes in urologic oncology. He has been instrumental in developing innovative surgical procedures for patients with bladder cancers.

Dr. Steinberg's research includes developing new treatments for urologic cancers, especially bladder cancer. He has performed over 2500 radical cystectomies and is a national leader in continent urinary tract reconstruction. He was the principal investigator for a regenerative medicine project using patient's own stem cells to create urinary tract reconstructions without using the intestine. He has been a national principal investigator, scientific advisor and protocol development advisor for multiple innovative clinical trials and translational research studies utilizing novel agents including oncolytic vaccines and immunotherapeutic agents. He has been a key advisor in clinical trial design, protocol development, study completion and analysis for patients with high-risk non-muscle invasive bladder cancer.

In addition, he is also involved with additional innovative intravesical drug delivery systems and other immunotherapy translational research studies. He has been a key protocol advisor on a number of novel neoadjuvant and adjuvant therapy trials for patients with muscle invasive bladder cancer and is currently leading the development of personalized cancer vaccines for neoadjuvant and metastatic bladder cancer. He has created a bladder cancer tissue bio-bank and has been a key participant in The Cancer Genome Atlas (TCGA) project for muscle invasive bladder cancer. He has been actively investigating genomic factors involved in therapeutic response.

Lastly, he has collaborated with investigators to create nude mouse human bladder cancer xenografts. Dr. Steinberg is also the former chairperson of the Scientific Advisory Board of the Bladder Cancer Advocacy Network and serves on the executive committee of the Bladder Cancer Research Network. He has published over 250 peer review and book chapters

Seth Lerner, MD

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Noah Hahn, MD

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Session 3: Risk Stratification and Definition of Disease States, Bladder-Intact and High-Grade Event-Free Survival

Ashish Kamat, MD (Presenter)



Dr. Ashish M. Kamat is Professor of Urologic Oncology (Surgery) and Cancer Research at UT MD Anderson Cancer Center, Houston.

Dr Kamat serves as founding President of International Bladder Cancer Group (IBCG) and co-President of the International Bladder Cancer Network (IBCN), Associate Editor for European Urology Oncology, Editor for UroToday Bladder Cancer Center of Excellence, Chair of the SIU Innovators Committee. He is an active member of the American Urologic Association, having served on the board of various committees, guidelines panels, and leadership and mentor groups, and is an alumnus of the AUA Leadership Program.

Dr. Kamat's expertise is in urologic oncology and his active research portfolio in this area has resulted in over 375 publications. He is listed in Who's Who in Medicine and Best Doctors in America, has won the Compassionate Doctor Award from patient groups and is active in national and global patient advocacy efforts. Dr. Kamat directed the MDACC Urologic Oncology Fellowship from 2005-2016 and in 2016, an endowment was created in his honor, the "Wayne B. Duddlesten Professorship in Honor of Dr Ashish Kamat" for his work in Cancer Research and Education.

Maria Ribal, MD, PhD (Presenter)



Maria J. Ribal received her medical degree in 1994, followed by her PhD in 2002, both at the University of Barcelona. Specialist in Urology in 1999 after 5 years residency at the Hospital Clínic in Barcelona. She did a research Fellowship with an Investigation Grant at the Hospital Clinic in 2000-2001. She attended as Visiting Clinician at Mayo Clinic in Rochester (USA) in 2002. Fellow in Laparoscopic Surgery at the University College London Hospital (UCLH) from June till December 2006. She was member of the Oncology Unit of the Department of Urology at Fundacio Puigvert (2002-2005).

Since February 2005, she is member of the Department of Urology at the Hospital Clinic, University of Barcelona. Currently, she is Associate Professor of Surgery at the University of Barcelona from 2005 till present. From December 2011 she is the Head of the Multidisciplinary Unit of Uro- Oncology at Hospital Clinic. Her main interests include urologic oncology, major oncologic surgery, laparoscopic surgery and transplantation and genetic research of urological tumors. She is author of more than 120 publications, and more than 350 invited lectures at conferences and courses.

She is an active member of European Association of Urology: Member of the Muscle-Invasive and Metastatic Bladder Cancer Guidelines Group of the European Association of Urology (EAU) 2006-2020, Member of the ESUT Working group from European Association of Urology since 2010. Board member of the EUSP Office of the European Association of Urology since April 2012 till March 2020. Chair of the Dissemination Committee of the EAU Guidelines of the European Association of Urology from 2016-

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2021. Board member of EAU Guidelines office since January 2016. Vice-chair of the EAU Guidelines Office since 2019. Chair of the EAU Guidelines Office from July 2021. In 2009, during the EAU Annual Meeting held in Stockholm, she has received the Crystal Matula award from de EAU.

Paul Kluetz, MD (Presenter)



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 has a broad interest in trial design and endpoint selection 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.

Charles Viviano, MD, PhD (Moderator)



Dr. Viviano is Clinical Deputy Office Director in the Office of GastroRenal, ObGyn, General Hospital, and Urology Devices (OHT3) in the Center for Devices and Radiological Health at the Food and Drug Administration. He is a board-certified Urologist. Upon joining the FDA in 2015, he was the sole Urology medical officer in CDRH responsible for the clinical review of all urologic devices, including the first submissions for high intensity focused ultrasound devices for prostate ablation. He is also a founding committee member for the SPARED Coordinated Registry Network for prostate ablation devices and the principal investigator for an FDA-led project identifying patient preferences in prostate cancer treatment.

He currently remains involved in the regulatory review of urologic devices across the total product lifecycle, in addition to serving as the senior medical officer in OHT3. Prior to joining the FDA, he was an Assistant Professor in the Division of Urology at Duke University where his practice focused on General Urology and Men's Health. Prior to Duke, he was in private practice in Connecticut. He received his medical education at the University of Connecticut and his PhD in Toxicology from the University of North Carolina at Chapel Hill.

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Matthew Galsky, MD



Dr. Galsky is a medical oncologist with a clinical and research focus on bladder cancer. He completed a medical oncology fellow at Memorial Sloan-Kettering Cancer Center (MSKCC) and subsequently joined the faculty at MSKCC.

In 2010, he was recruited to Mount Sinai School of Medicine/Tisch Cancer Institute where he currently serves as Professor of Medicine and Director of Genitourinary Medical Oncology, Co-Director of the Center of Excellence for Bladder Cancer, Associate Director for Translational Research, and Co-Leader of the Cancer Clinical Investigation Program. His research efforts involve team science-based approaches to dissect the mechanisms underlying response and resistance to treatment strategies in bladder cancer with a focus on immunotherapeutic approaches.

Rick Oliver



Mr. Rick Oliver, patient advocate, diagnosed with bladder cancer in the fall of 2018 NMIBC TAHG, unresponsive to BCG treatments. Restaged twice in 2019 NMIBC T1HG. In May 2019 elected to have a radical cystectomy with an ileal conduit diversion. Pathology results after the RC, lymph nodes clear, ureter left side had cancer at the throat of the bladder, prostate was cancerous (not known prior to surgery) Margins clear, final staging was T2aHG.

Currently a patient advocate for the CISTO clinical trial study, participated in a few clinical trials for bladder cancer involving quality of life and decision-making processes. Assisted with the development and was a panel member for the BCAN webinar “Thinking Through Decision-Making: Keeping a grip on the emotional rollercoaster when bladder cancer returns after BCG”. Actively involved with the local bladder support group and involved with other bladder cancer support groups outside my local area.

Ashish Kamat, MD

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Paul Kluetz, MD

(See above)

Maria Ribal, MD, PhD

(See above)

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Wrap-up Day 1

Jaleh Fallah, MD



Dr. Fallah is a medical oncologist at the Division of Oncology 1, Genitourinary Cancers, US FOOD & Drug Administration (FDA). Dr. Fallah received her M.D. from Isfahan University of Isfahan in Iran. She then moved to the United States, where she completed her Internal Medicine residency at Brown University and her Hematology and Oncology fellowship at Cleveland Clinic.

Her clinical interests are GU malignancies, brain metastasis, and biomarkers. During her fellowship training, she wrote protocols for several clinical trials in bladder cancer and brain tumors. Upon completion of her fellowship training in 2020, she joined FDA as a clinical reviewer. During this time, she has evaluated trial designs as well as safety and efficacy of therapeutics in all stages of clinical development from pre-investigational new drugs through marketing approvals and has worked on several exploratory pooled analyses.