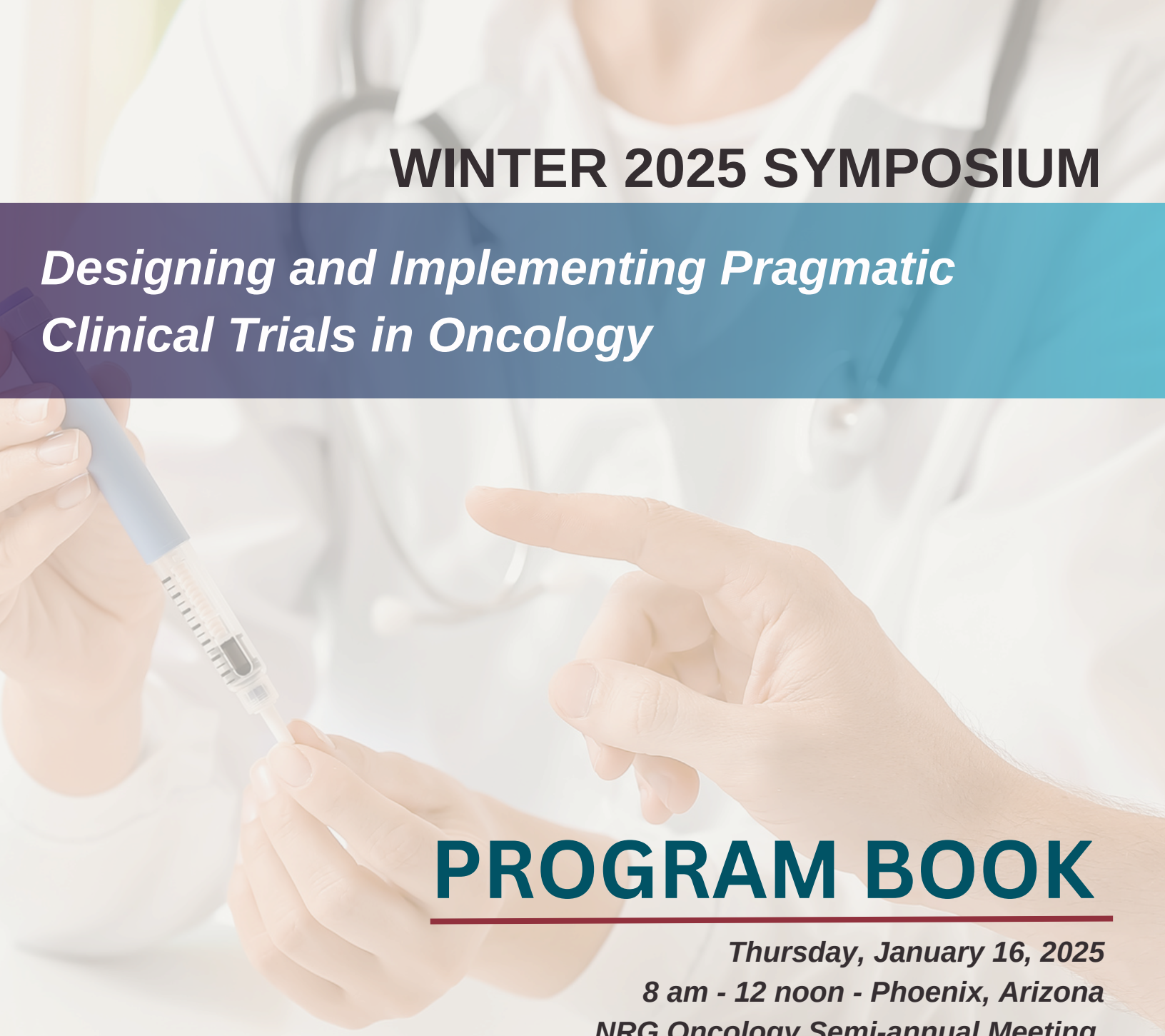
# WINTER 2025 SYMPOSIUM

## *Designing and Implementing Pragmatic Clinical Trials in Oncology*



# PROGRAM BOOK

***Thursday, January 16, 2025***
***8 am - 12 noon - Phoenix, Arizona***
***NRG Oncology Semi-annual Meeting***

***SPONSORED BY*** GOG FOUNDATION® *Transforming the standard of care* NRG ONCOLOGY *Advancing Research. Improving Lives.™*

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# FACULTY DISCLOSURE INFORMATION

## Winter 2025 Symposium
## *"Designing and Implementing Pragmatic Clinical Trials in Oncology"*
## January 16, 2025
## Phoenix, Arizona

In accordance with the ACCME Accreditation Criteria, The GOG Foundation, Inc., as the accredited provider of this activity, must ensure that anyone in a position to control the content of the educational activity has disclosed all relevant financial relationships with any **ineligible company *(**formally known as commercial interests). **All Committee/Planning/Faculty members** were required to disclose all financial relationships and speakers were required to disclose any financial relationship **as it pertains to the content of the presentations**.

The ACCME does not consider providers of clinical service directly to patients to be an ineligible company. "Relevant" financial relationships are financial transactions (in any amount) occurring within the past 24 months that may create a conflict of interest.

Please note we have advised the speakers that it is their responsibility to disclose at the start of their presentation if they will be describing the use of a device, product, or drug that is not FDA approved or the off-label use of an approved device, product, or drug or unapproved usage. The requirement for disclosure is not intended to imply any impropriety of such relationships, but simply to identify such relationships through full disclosure, and to allow the audience to form its own judgments regarding the presentation.

**All of the relevant financial relationships listed for these individuals have been mitigated.** However, if you perceive a bias during a session, please report the circumstances on the session evaluation form.

**NEW TERM ***An **"ineligible company"** is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

| NAME | Individual's Role(s) in Activity | Nothing To Disclose | Name of Ineligible Company(s) | Nature of Relevant Financial Relationship(s) |
|---|---|---|---|---|
| ***Planning Disclosures*** | | | | |
| Ying Liu, MD, MPH | **Program Chair** | | AstraZeneca; GSK; Artios Pharma; Repare Therapeutics; Myriad Genetics | Advisory Board (Myriad Genetics)<br>Research funding (AstraZeneca; GSK; Artios Pharma; Repare Therapeutics) |
| Carol Aghajanian, MD | **Co-Chair** | | Astra Zeneca; Merck; WCG; Astra Zeneca (MSK PI) | Advisory Board (Astra Zeneca; Merck)<br>Clinical Trial funding to institution (MSK) (Astra Zeneca (MSK PI))<br>DMC (WCG) |
| ***Speaker Disclosures*** | | | | |
| Carol Aghajanian, MD | **Moderator/ Speaker** | | Astra Zeneca; Merck; WCG; Astra Zeneca (MSK PI) | Advisory Board (Astra Zeneca; Merck)<br>Clinical Trial funding to institution (MSK) (Astra Zeneca (MSK PI))<br>DMC (WCG) |
| Dorothy Erlanger | **Speaker** | **X** | | |
| Elaina Harper, BS | **Speaker** | **X** | | |
| Ying Liu, MD, MPH | **Moderator/ Speaker** | | AstraZeneca; GSK; Artios Pharma; Repare Therapeutics; Myriad Genetics | Advisory Board (Myriad Genetics)<br>Research funding (AstraZeneca; GSK; Artios Pharma; Repare Therapeutics) |
| Sara McCartney, MS, RN | **Speaker** | **X** | | |
| Neal Meropol, MD | **Speaker** | | Flatiron Health; Roche | Employee (Flatiron Health)<br>Equity ownership (Roche) |
| Meg Mooney, MD, MS | **Speaker** | **X** | | |
| Kathleen Moore, MD | **Speaker** | | Research To Practice; Company: Prime Oncology; Great Debates and Updates; Corcept; Abbvie; Nykode Therapeutics; third arc; Astellas | Honoraria (Research To Practice; Company: Prime Oncology; Great Debates and Updates; Corcept; Abbvie; Nykode Therapeutics; third arc; Astellas Medivation |

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|---|---|---|---|---|
| | | | Medivation; GOG Partners; NRG Ovarian Committee Chair; Genentech/Roche; Immunogen; AstraZeneca; Merck; Eisai; Verastem/Pharmacyclics; AADi; Caris Life Sciences; Iovance Biotherapeutics; Janssen Oncology; Regeneron; zentalis; Daiichi Sankyo Europe GmbH; Novacure; BioNTech SE; immunocore; Sanofi/Aventis; seagen; Takeda Science Foundation; zymeworks; profound bio; Mersana; Blueprint pharmacetuicals; GSK/Tesaro; Duality Biologics; Artios; Amgen; Schrodinger; Daiichi Sankyo/Lilly; Regeneron; Up to Date; BioNTech SE | Leadership (GOG Partners; NRG Ovarian Committee Chair)<br>Consulting or Advisory Role (Genentech/Roche; Immunogen; AstraZeneca; Merck; Eisai; Verastem/Pharmacyclics; AADi; Caris Life Sciences; Iovance Biotherapeutics; Janssen Oncology; Regeneron; zentalis; Daiichi Sankyo Europe GmbH; Novacure; BioNTech SE; immunocore; Sanofi/Aventis; seagen; Takeda Science Foundation; zymeworks; profound bio; Mersana; Blueprint pharmacetuicals; GSK/Tesaro; Duality Biologics; Schrodinger)<br>Research Funding (Merck; Regeneron; Verastem; AstraZeneca; Immunogen; Artios; Amgen; Daiichi Sankyo/Lilly; Immunocore)<br>Patents, Royalties, Other Intellectual Property (Up to Date)<br>Travel, Accommodations, Expenses (BioNTech SE) |
| Mei-Yin Polley, PhD | **Speaker** | | Neuro Trials, LLC | Consultant |
| Bhavana Pothuri, MD, MS | **Speaker** | | AstraZeneca; celsion/Immunon; Clovis Oncology, Inc.; Genentec; Eisai; GlaxoSmithKline; GOG foundation; Imab; Immunogen; Incyte Corporation; Karyopharm Therapeutics; Merck; Mersana; Seagen Inc.; Sutro; Toray Industries | Consultant (AstraZeneca; Eisai; GlaxoSmithKline; GOG foundation; Merck; Mersana; Seagen Inc.; Sutro)<br>Grant/Contract (AstraZeneca; celsion/Immunon; Clovis Oncology, Inc.; Genentec; GlaxoSmithKline; Imab; Immunogen; Incyte Corporation; Karyopharm Therapeutics; Merck; Mersana; Seagen Inc.; Sutro; Toray Industries) |
| Karen L. Reckamp, MD | **Speaker** | | Amgen, AstraZeneca, Blueprint, Daiichi Sankyo, EMD Sereno, Genentech, GlaxoSmithKline, Janssen, Lilly, Mirati; Calithera; Elevation Oncology | Consultant w/ Honoraria to Self (Amgen, AstraZeneca, Blueprint, Daiichi Sankyo, EMD Sereno, Genentech, GlaxoSmithKline, Janssen, Lilly, Mirati)<br>Research Funding to Institution (Genentech; Blueprint; Calithera; Daiichi Sankyo; Elevation Oncology; Janssen) |
| James C. Yao, MD | **Speaker** | | Acrotech Biopharma; Exelixis; HutchMed | Consultant |
| Jonathan Yang, MD, PhD | **Speaker** | | AstraZeneca; Kazia Therapeutics; Plus Therapeutics; Debiopharm; Biocept; Cantex Therapeutics | Consultant (AstraZeneca; Kazia Therapeutics; Plus Therapeutics)<br>Contracted Research (Debiopharm; Biocept; Cantex Therapeutics) |
| Michelle N Small, MPH | **Staff** | **X** | | |
| Jill Reese | **Staff** | **X** | | |
| Holley Engbert | **Staff** | **X** | | |
| Angeles Alvarez Secord, MD | **Edu Chair** | | AZ, Abbvie; Aravive; Clovis, Eisai, Ellipses Pharma, Roche/Genentec ; GSK; I-MAB Biopharma; Immunogen; Karyopharm; Merck; Mersana; Seagen; VBL Therapeutics; Zentalis; Gilead; Oncoquest/Canaria BIo | Research funds to institution (AZ, Abbvie; Aravive; Clovis; Eisai; Ellipses Pharma; Roche/Genentec; GSK; I-MAB Biopharma; Immunogen; Karyopharm; Merck; Mersana; Seagen; VBL Therapeutics; Zentalis; Oncoquest/Canaria BIo)<br>Adboard (Abbvie)<br>Uncomp AdBoard (Gilead; Oncoquest/Canaria Bio; Aravive; VBL )<br>SteeringCommitte (Aravive; VBL; Oncoquest/Canaria Bio) |

# CONTINUING MEDICAL EDUCATION (CME)


## Accreditation Statement

The GOG Foundation, Inc. is accredited by the ACCME to provide Continuing Education for physicians.

## AMA PRA Category 1 Credits™

The GOG Foundation, Inc. designates this live activity for a maximum of **4 AMA PRA Category 1 Credits™**.

Physicians should claim only the credit commensurate with the extent of their participation in the activity.

## The GOG Foundation Inc. Continuing Education (CME) Program Mission Statement

The purpose of The GOG Foundation, Inc. CME program is to provide and promote an infrastructure dedicated to enhancing the knowledge base of meeting participants and guests centered on the development, execution, analysis and application of GOG-supported clinical trials. To that end, the CME Program engages in these discussions member researchers and invited clinicians committed to reducing the risk and improving outcomes for women at risk for or afflicted with a gynecologic malignancy.

## Disclosure Declaration

In compliance with ACCME regulations, The GOG Foundation, Inc., as the accredited provider of this activity, must ensure that anyone in a position to control the content of the educational activity has disclosed all relevant financial relationships with any commercial interest. All reported conflicts are managed by a designated official to ensure a bias-free presentation. Please see the complete disclosure list included with this program.

## How do I collect CME Certificates?

***Evaluation Link and QR code***

**https://s.pointerpro.com/winter25sym**

- **Scan QR code or click link** above to complete evaluation.
- **Click submit** and your certificate will automatically be emailed to you.

**CME Evaluations must be submitted by: February 3, 2025.**

If you have issues accessing your certificate or questions about CMEs, please contact: cmeinfo@gog.org.

## Slide Presentations

A PDF version of all final slide presentations are available in the Symposium Session content on the Attendee Hub and the Meeting App

For questions or comments about this CME activity, please contact: Michelle N. Small, MHA
Dir, Education Programs/CME Compliance
at msmall@gog.org

Winter 2025 Symposium

# *Designing and Implementing Pragmatic Clinical Trials in Oncology*

Thursday, January 16, 2025
8 am - 12 noon - Phoenix, Arizona
NRG Oncology Semi-annual Meeting

**Program Chair: Ying Liu, MD, MPH, Co-Chair: Carol Aghajanian, MD**

**Target Audience:** This educational activity is directed towards members and non-members including our broad audience of physicians, research staff, new investigators, clinical research associates, basic researchers, medical physics, clinical trial nurses, patient advocates and other health care professionals interested in the treatment of cancer.

**Program Description:** A new type of trial design is coming to NRG. The upcoming Winter 2025 Educational Symposium will highlight the value of pragmatic clinical trials across oncology and include examples of trials in lung, breast, and gynecologic cancers. This symposium is for everyone involved in oncology clinical trials and will help define the role of pragmatic trials and the effect of treatment in routine clinical practice. The speakers will focus their presentations on the design and conduct of pragmatic clinical trials, review the regulatory landscape, and describe the components of a successful pragmatic clinical trial, including how to improve health equity in clinical trials. The session will include didactic lectures from content experts as well as case studies from current NRG trials. The symposium will also incorporate question and answer sessions for audience participation. The speakers represent a multidisciplinary team, including the patient perspective.

Learning Objectives:

Following this activity, participants will be better able to:

- 1. Define and clarify the key components of a pragmatic clinical trial
- 2. Explain the role of pragmatic clinical trials in conducting effective clinical research in real-world settings
- 3. Design and implement effective pragmatic clinical trials to enroll more diverse patient populations

## Continuing Education

**Accreditation Statement:** The GOG Foundation, Inc. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education for physicians.

**AMA PRA Category 1 Credits™:** The GOG Foundation, Inc. designates this live internet activity for a maximum of ***4 AMA PRA Category 1 Credits™***. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**Evaluation:** Participants who complete the educational activity, evaluation and attendance verification will receive a certificate of credit.

**Presentation agenda on next page**

# Winter 2025 Symposium Agenda

## *"Designing and Implementing Pragmatic Clinical Trials in Oncology"*

**Jan 16, 2025 – 8 am to 12 pm (MT) - NRG Oncology Winter 2025 Meeting – Phoenix, AZ**

***Program Chair: Ying Liu, MD, MPH, Co-Chair: Carol Aghajanian, MD***

**Presentation Agenda**

| Time | Topic/Title | Speaker/Moderator |
|---|---|---|
| 8:00 am | **Welcome/Opening Remarks** | |
| **8:05 am** | **Session 1: Introduction to Pragmatic Clinical Trials** | **Moderator: Carol Aghajanian, MD** |
| 8:05 – 8:15 | What is a Pragmatic Clinical Trial? | Kathleen Moore, MD |
| 8:15 – 8:30 | Why are Pragmatic Clinical Trials Important? NIH Perspective | Meg Mooney, MD, MS |
| 8:30 – 8:45 | Lung Pragmatica Trial | Karen L. Reckamp, MD |
| **8:45 – 9:00** | **Q/A** | |
| **9:00– 9:10** | **Break** | |
| **9:10 am** | **Session 2: Designing a Pragmatic Clinical Trial** | **Moderator: Ying Liu, MD, MPH** |
| 9:10 – 9:25 | Eligibility Criteria – Practicality and Inclusivity | Carol Aghajanian, MD |
| 9:25- 9:40 | Incorporating Pragmatic Elements Into Oncology Trial Designs | Mei-Yin Polley, PhD |
| 9:40 – 9:55 | Leveraging Technology and Real-World Data to Streamline Trials | Neal Meropol, MD |
| 9:55-10:10 | Optimizing the EHR for Pragmatic Clinical Trials | James C. Yao, MD |
| 10:10 – 10:25 | How to Reach Diverse Populations and Improve Health Equity | Bhavana Pothuri, MD, MS |
| **10:25 – 10:40** | **Q/A** | |
| **10:40 – 10:50** | **Break** | |
| **10:50 am** | **Session 3: Implementing a Pragmatic Clinical Trial** | **Moderator: Carol Aghajanian, MD** |
| **10:50 – 11:05** | NRG-GY036: Case Study for a Pragmatic Clinical Trial | Ying Liu, MD, MPH |
| **11:05– 11:20** | NRG-BN014: Case Study for a Pragmatic Clinical Trial | Jonathan Yang, MD, PhD |
| **11:20 - 11:30** | Logistics of Data Management and AE Reporting | Elaina Harper, BS<br>Sara McCartney, MS, RN |
| **11:30– 11:40** | Patient Perspective on Pragmatic Clinical Trials | Dorothy Erlanger |
| **11:40 – 11:55** | **Q/A** | |
| **11:55- 12:00 pm** | **Closing Remarks** | Ying Liu, MD, MPH |

# SYMPOSIUM FACULTY

## PROGRAM CHAIR/SPEAKER/MODERATOR

**Ying Liu, MD, MPH**
Assistant Attending, Gynecologic Medical Oncology
Clinical Genetics Service
Lead, Inherited GYN Cancers Program
Memorial Sloan Kettering Cancer Center

Ying Liu, MD, MPH is an assistant attending at Memorial Sloan Kettering Cancer Center with dual appointments in gynecological medical oncology and clinical genetics. She received her Bachelor of Science degree with distinction in Biochemistry from UNC-Chapel Hill with a Morehead-Cain Scholarship. She then went on to obtain her MD from Duke University while simultaneously receiving her MPH from UNC-Chapel Hill via a joint program. She completed internal medicine residency at Columbia University Medical Center where she was then selected to serve an additional chief residency year. She graduated from the medical oncology fellowship at Memorial Sloan Kettering Cancer Center where she joined the faculty in early 2020. She specializes in caring for women with gynecological (GYN) cancers including ovarian, uterine (endometrial), cervical, and other rare GYN cancers. She has a special interest in inherited cancers and provides counseling and genetic testing for patients with all different types of cancers. Her research involves studying the genetic and genomic drivers of cancer and how they influence the development of disease. She is the principal investigator of several, novel therapeutic trials for gynecologic cancers. She also has a special interest in health disparities and improving access to genetic testing and cancer care for women of diverse backgrounds.

## PROGRAM CO-CHAIR

**Carol Aghajanian, MD**
Chief, Gynecologic Medical Oncology Service, Director
MSK NCI Network Program
Avon Chair in Gynecologic Oncology Research
Member, Memorial Sloan Kettering Cancer Center
Professor of Medicine, Weill Cornell Medical College

Carol Aghajanian, MD, a medical oncologist, is the Chief of the Gynecologic Medical Oncology Service at Memorial Sloan Kettering Cancer Center and Professor of Medicine at Weill Cornell Medical College. She serves as Chair of the Gynecologic Cancer Committee of NRG Oncology. She is the Principal Investigator for the MSK, National Clinical Trials Network (NCTN), Lead Academic Participating Site (LAPS) grant. Her research focuses on developmental therapeutics as applies to gynecologic cancers. She has earned several rewards in recognition of her work including the MSK Louise and Allston Boyer Award for Distinguished Achievement in Biomedical Research (2003), the Visionary Medical Research Honoree by the Ovarian Cancer National Alliance (2012), the Michaele C. Christian Oncology Development Award (2014), the Harry Long Multidisciplinary Award, Society of Gynecologic Oncology (2017), the Willet F. Whitmore Award for Clinical Excellence (2020), and the Avon Chair in Gynecologic Oncology Research (2023). In 2024, Dr. Aghajanian was inducted into the Giants of Cancer.

# SPEAKERS

**Dorothy Erlanger**
Chair
NRG Oncology Patient Advocate Committee (PAC)

Dorothy Erlanger is a dedicated patient advocate and a 23-year survivor of advanced ovarian cancer. As the Chair of the Patient Advocate Committee for NRG Oncology, she works to enhance the preparation and excellence of the entire advocate team, making a significant impact across NRG initiatives. Dorothy also contributes to the PCOR committee, the Older Adult Special Interest Group, Health Disparities Committee and Ovarian Committee.
A presenter for the Survivors Teaching Students™ program, Dorothy shares her journey with medical students to enhance awareness of ovarian cancer symptoms in future healthcare providers. She also serves on the Massey Cancer Center advisory board and is a member of Cancer Dancer, a group advocating for women with gynecologic cancers.

Dorothy's commitment to advancing science and advocacy is inspired by her multigenerational medical heritage. This spring, she will proudly hand off "custody" of her grandfather's Nobel Prize Medal in Physiology to the American Physiological Society and will speak at their annual conference about this remarkable legacy.
And, as an aside, Dorothy is also an IRONMAN® triathlete and has qualified for 2025 Team USA. She'll be competing at the World Championships in Australia in October.
Putting that all together? A passion for overcoming challenges, living to the fullest and giving back wherever possible.

**Elaina L. Harper, BS**
Director of Data Management
NRG Oncology, SDMC

Elaina L. Harper, BS has supported cooperative group data management efforts for over 20 years. Elaina first joined the NSABP Data Management team in 2002 after obtaining a BS degree in Mathematics from the University of Pittsburgh. Over the course of working with the NSABP group through 2014, and since then with NRG Oncology, Elaina has been involved in various areas of data management including the evolution of paper data management to the implementation of an EDC. Experienced in case report form design, CTSU OPEN entry requirements and study configuration in Medidata Rave, Elaina has served on several working groups over the years including the CSC Data Quality Working Group, CSC Standard End Users Working Group, and most recently the NCI Streamlining Clinical Trials Implementation Committee.

# SPEAKERS

**Sara McCartney, MS, RN**
Senior Adverse Events Specialist
NRG Oncology

Sara McCartney, MS, RN has over 13 years of NCI Cooperative group clinical trials experience focused on expedited adverse event report review, regulatory safety reporting, site education, and protocol development support. Sara began her career with the RTOG Protocol Development and Regulatory Compliance (PDRC) department in 2011 and continues to support PDRC with NRG Oncology since 2014. Prior to her clinical trial experience, Sara was a nurse in the surgical trauma ICU at the University of Pennsylvania, as well as the department of interventional radiology. Sara holds a BA in psychology and philosophy from Franklin and Marshall College, an MS in biobehavioral health from the Pennsylvania State University, and a BSN from Thomas Jefferson University.

**Neal J. Meropol, MD**
Vice President of Research Oncology
Flatiron Health

Neal J. Meropol, MD is a medical oncologist, clinical investigator, outcomes researcher and health tech executive, currently serving as Vice President of Research Oncology at Flatiron Health. In this role, he oversees the clinical teams supporting retrospective and prospective evidence generation, providing scientific and clinical leadership in leveraging Flatiron's EHR-based technology platforms to streamline drug development and inform patient care. A major focus is the development and application of innovations to leverage real world data (both retrospective and prospective) to learn from the experience of every cancer patient and enable clinical research to take place wherever care is delivered.

Dr. Meropol previously served as chair of the NCI Clinical Trials and Translational Research Advisory Committee (CTAC), co-chair of the NCI Streamlining Clinical Trials Working Group, and chair of the NCI Gastrointestinal Cancer Steering Committee. He completed a four-year term as an elected member of the American Society of Clinical Oncology (ASCO) Board of Directors. A committed educator, Dr. Meropol was chair of the AACR/ASCO Methods in Cancer Clinical Research Workshop, and ASCO Leadership Development Program. He has authored more than 300 manuscripts, book chapters, and editorials related to cancer prevention, treatment, decision making and health economics.

# SPEAKERS

**Meg Mooney, MD, MS**
Associate Director, Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute, National Institutes of Health

Meg Mooney, MD, MS received her medical degree from the University of Chicago Pritzker School of Medicine in Chicago and her general surgical training at the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. She completed her Surgical Oncology fellowship training at the Roswell Park Cancer Institute in Buffalo, New York and also holds a Masters of Science degree in Management from the Massachusetts Institute of Technology in Cambridge, Massachusetts.

Dr. Mooney joined the US National Cancer Institute in 2002 as Head of Gastrointestinal and Neuroendocrine Cancer Therapeutics in the Clinical Investigations Branch in the Cancer Therapy Evaluation Program (CTEP) and became the Associate Director of CTEP in April 2020. In her capacity as the CTEP Associate Director, she has oversight and coordination responsibilities for the programmatic, financial, and administrative functions for a broad, multidisciplinary, clinical research effort to coordinate and conduct phase 1 through phase 3 clinical trials testing new therapies and precision-medicine, multi-modality, approaches for cancer treatment in national clinical trials network programs covering over 1,800 sites and accruing over 20,000 patients annually in the US and internationally. She also serves as the Institutional Official for the NCI CIRB covering several NCI-supported extramural clinical trials network programs

**Kathleen N. Moore, MD, MS, FASCO**
Deputy Director
Co-Director Cancer Therapeutics Program
Stephenson Cancer Center at OU Health
Professor, Gynecologic Oncology
University of Oklahoma, HSC

Kathleen Moore, MD, is Deputy Director of the Stephenson Cancer Center and professor in the Department of Obstetrics and Gynecology at Stephenson Cancer Center (SCC), University of Oklahoma. She earned her MD from the University of Washington, followed by a residency in obstetrics-gynecology at Magee-Womens Hospital in Pittsburgh, and a fellowship in gynecologic oncology at the University of Oklahoma Health Sciences Center.

Dr Moore is principal investigator for SCC's National Cancer Institute U10 National Clinical Trials Network Lead Academic Participating Site award, the SCC UM1 ETCTN award, and MPI on the SCC Cancer Screening Research Network UG1. In these roles, she oversees clinical research development and operations. She works to establish collaborations between scientists and clinicians to develop translational and biomarker-driven studies and clinical trials, and develop the infrastructure for clinical trials and translational research.

*Continued on next page*

# SPEAKERS

*Kathleen Moore Bio -Continued*

She has leveraged success in some of these trials into more directed studies in specific gynecologic populations in an attempt to move promising agents into larger, more accessible trials through the cooperative-group mechanism. She has overseen phase I trials and safety lead-ins for her site since 2009.

Dr Moore serves as chair of NRG's Ovarian Cancer Committee, and as a member of the Developmental Therapeutics Committee and on the GOG Foundation BOD. She is a member of the American Society of Clinical Oncology and was elected to the BOD.. Her research has appeared in several respected peer-reviewed publications, including the Journal of Clinical Oncology, New England Journal of Medicine, Cancer, and Clinical Cancer Research.

**Mei-Yin C. Polley, PhD**
Head of the Statistics Division, NRG Statistics and Data Management Center (SDMC)
Professor (Biostatistics), Dept. of Public Health Sciences
University of Chicago

Mei Polley, PhD, is Professor of Biostatistics in the Department of Public Health Sciences at the University of Chicago. She also serves as the Head of the Statistics Division of the NRG Oncology Statistics and Data Management Center (SDMC) and the Lead Statistician for the Brain Tumor Committee for NRG Oncology, a National Cancer Institute (NCI) sponsored member of the National Clinical Trials Network (NCTN) group. Dr. Polley has nearly two decades of experience as a cancer clinical trial biostatistician and is a widely recognized expert in clinical trial methodology. Her statistical methods research has spanned a variety of areas including early-phase clinical trial designs, biomarker reproducibility, innovative group sequential methods for biomarker validation, prognostic and predictive modeling, and design and analysis of biomarker-based clinical trials. Over the span of her scientific career, she has held many influential positions as a statistical advisor and has served on numerous national scientific governing or advisory bodies including the Federal Advisory Committee of the US Department of Veterans Affairs (VA), the Scientific Committee of American Society of Clinical Oncology (ASCO), and the Scientific Committee of the CNS Clinical Trials conference, among many others. She has been competitively elected to many national scientific committees including the NCI/NCTN Steering Committees for trials in lymphoma and head and neck cancer. Since 2022, Dr. Polley has served on the Editorial Board of Neuro-Oncology, the primary journal of the Society of Neuro-Oncology (SNO).

# SPEAKERS

**Bhavana Pothuri, MD, MS**
Professor, Departments of Ob/Gyn and Medicine
NYU Grossman School of Medicine
Medical Director, Clinical Trials Office (CTO)
Director, Gynecologic Oncology Clinical Trials
Director, Gynecologic Oncology Research
Laura & Isaac Perlmutter Cancer Center

Bhavana Pothuri, MD, MS is a Professor in the Departments of Obstetrics and Gynecology and Medicine at the New York University (NYU) School of Medicine, Medical Director of Clinical Trials Office (CTO), Director of Gynecologic Oncology Clinical Trials, Director of Gynecologic Oncology Research, and Site Principal Investigator for the Perlmutter Cancer Center, NYU Langone Health. Her roles nationally include: Gynecologic Oncology (GOG) Foundation Director of Diversity and Health Equity for Clinical Trials, GOG Partners, Associate Clinical Trials Advisor (Ovary and Endometrial Cancer), Society of Gynecologic Oncology Board of Directors, SGO Co-Chair COVID-19 Task Force, and NY Obstetrical Society (NYOB) Executive Council, Treasurer.

Dr. Pothuri earned her medical degree from Jefferson Medical College at Thomas Jefferson University. She completed her residency in Obstetrics and Gynecology at the Jefferson Health System and a fellowship in Gynecologic Oncology at Memorial Sloan Kettering Cancer Center. Dr. Pothuri has substantially contributed to groundbreaking research in use of the PARP inhibitor, niraparib as frontline maintenance treatment for ovarian cancer, as well as dostarlimab, PD-1 inhibitor in endometrial cancer. Both of these agents have been FDA approved for their respective disease sites. She is also passionate about diversity and equity and in her new role on the GOG Foundation will help bring her efforts to improve minority and underrepresented patients in clinical trials to a national level.

**Karen Reckamp, MD, MS**
Professor
Medical Oncology Director, Lung Institute
Director, Division of Medical Oncology
Associate Director, Clinical Research
Cedars-Sinai, Cancer Institute

Karen L. Reckamp, MD, MS is Clinical Professor in Medicine, Director of the Division of Medical Oncology at Cedars-Sinai Medical Center. She is also the Associate Director of Clinical Research for the Cedars Sinai Cancer Center, and Medical Oncology Director of the Women's Guild Lung Institute at Cedars Sinai Medical Center. She obtained her medical degree at the University of Chicago, Pritzker School of Medicine in 1998 with AOA distinction, and trained in Internal Medicine at Washington University's Barnes Jewish Hospital. Dr. Reckamp completed fellowship training in Hematology/Oncology at the David Geffen School of Medicine, UCLA in June 2004, and completed a Master of Science degree in Clinical Research (MSCR).

*Continued on next page*

# SPEAKERS

*Karen Reckamp Bio-continued*

Dr. Reckamp serves as Chair for the Association of American Cancer Institute's Physician Clinical Leadership Initiative. She leads many phase I, II and III studies funded by the NCI, internal funds and industry. Dr. Reckamp is a member of ASCO, AACR, International Association for the Study of Lung Cancer, and SWOG. She is vice Chair of the SWOG Lung MAP platform. She participated in the ASCO Leadership Development Program and led the Scientific Committee for metastatic lung cancer for the ASCO annual meeting. Dr. Reckamp has been the past recipient of many honors including American Lung Association, Lung Force Honoree in 2018. She has also authored or co-authored many manuscripts in the field of Thoracic Oncology in high impact journals, including the New England Journal of Medicine and Journal of Clinical Oncology

**Jonathan T. Yang, MD, PhD**
Associate Professor, Dept of Rad Oncology
New York University School of Medicine

Jonathan T. Yang, MD, PhD, is an Associate Professor at New York University School of Medicine Department of Radiation Oncology. He serves as the Director of Clinical Research for the Laura and Isaac Perlmutter Cancer Center-Brain and Spine Tumor Center. He is also the Associate Vice Chair of Clinical Research and Developmental Therapeutics and the Director of Metastatic Disease Service in the Department of Radiation Oncology. His clinical and academic expertise is in central nervous system malignancies, metastatic disease, and precision radiation oncology through rational combination of novel therapeutics with radiotherapy.

**James C. Yao, MD**
Professor and Chair, Department
of Gastrointestinal Medical Oncology
University of Texas M.D. Anderson Cancer Center

James C. Yao, MD is professor and Chair, Department of Gastrointestinal Medical Oncology at University of Texas M.D. Anderson Cancer Center. He has been actively and continuously engaged with NCI-sponsored clinical trials program for over a decade; has led Phase I, II, and III studies through the NCI clinical trials system; and is the current MPI of the institution's UM1 grant titled, Texas EXperimental Cancer Therapeutic Network (UM1CA186688).

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# SPEAKERS

*James Yao Bio-continued*

Dr. Yao served as PI of the completed MDACC N01 (N01-CM-62202) and the U01 CA062461. He has extensive experience in taking promising agents through proof-of-concept phase 2 development into larger randomized multi-center studies. In the initial investigator-initiated study, Dr. Yao demonstrated significant clinical activity of everolimus in NETs as well as dose-dependent activity of the agent. Building on these data, Dr. Yao successfully led 4 multi-national studies. The RADIANT-3 phase 3 study demonstrated a 2.6-fold improvement in PFS and led to the first approval of a new agent for advanced pancreatic NETs in nearly three decades. RADIANT-4 phase 3 study in non-pancreatic NET of lung and GI origin also reported that everolimus significantly improved median PFS by almost threefold and led to the global approval of everolimus in these indications.

As well, Dr. Yao has a degree in Computer Science and experience in oncology informatics and EHR implementation and optimization. During the largest oncology installation of Epic at MD Anderson, Dr. Yao led the medical oncology effort including build, validation, treatment plan conversion, go-live; and optimization of the research protocol build post go-live. He led an effort to deploy ICD-O-3 that will improve the precision of oncology diagnoses in EHR and serves on the Epic Adult Oncology Steering Committee Board.

With his experience in both clinical trials and informatics, Dr. Yao is leading an NCI funded consortium to streamline clinical trial builds for EHR. The consortium is working to standardize build process and identify strategies to use reusable build modules to accommodate differences in formulary, workflow and SOP. The long-term goal is to enable single build by the consortium for each study that can be pushed to all sites that will activate the study with result of speeding up clinical trial activation and reducing cost. The consortium has made considerable progress and plans production sharing of protocols builds among consortium members in 2025.

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## *2025 Winter Symposium*
## *Designing and Implementing Pragmatic Clinical Trials in Oncology*

We would like to thank and acknowledge the following companies for providing Independent Medical Education (IME) grant support associated with the 2025 Winter Symposium

**PFIZER**

Thursday, January 16, 2025 - 8 am - 12 noon - Phoenix, Arizona
NRG Oncology Semi-annual Meeting