2023 DESIGN AND MANAGEMENT OF CANCER CLINICAL TRIALS COURSE

FRIDAY, SEPTEMBER 8
FRIDAY, SEPTEMBER 15
FRIDAY, SEPTEMBER 22
FRIDAY, SEPTEMBER 29
FRIDAY, OCTOBER 6
FRIDAY, OCTOBER 13

This **six-week course** teaches basic research concepts and principles that underlie the design and day-to-day conduct of cancer clinical trials. CME topics include:

- Phase I, II, III, and non-interventional trial design and statistics
- Responsibilities of a principal investigator (PI)
- Biomarkers, bioinformatics, and correlative studies
- Federal regulatory processes and funding mechanisms
- Patient-reported outcomes in clinical trials
- Panels on bench-to-bedside translation and maximizing productivity in clinical studies
- Case studies highlighting issues related to diversity, recruitment, and retention, accrual and financial feasibility, and ethical issues in clinical research

PROGRAM DIRECTOR | PLANNING COMMITTEE

Alan Pollack, M.D., Ph.D.
Professor and Chair of Radiation Oncology

Vaughn Edelson, M.P.H., M.P.A.
Sr. Project Manager, Education & Training

REGISTRATION AND INFORMATION

cvent.me/Bd4kqV

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

NCI Cancer Center
A Cancer Center Designated by the National Cancer Institute

Sponsored by the University of Miami Miller School of Medicine.

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OVERVIEW

Despite the exponential rate of progress in understanding the cellular and molecular biology of cancer, clinical oncology care has not fully incorporated these mechanistic insights. Accelerated improvement in the control and elimination of cancer will require clinical leaders with the following foundation:

- Thorough knowledge of clinical trial design and development.
- Understanding of the biology of different cancers and ability to identify and study relevant targets for drug and diagnostic development.
- Ability to understand, assimilate, and utilize new cellular and molecular biologic discoveries to develop innovative strategies for cancer treatment, detection, and prevention.
- Understanding of the strengths and limitations of laboratory investigation, and the importance of designing hypothesis-driven trials with relevant laboratory correlates.
- Working knowledge of the regulatory activities of the FDA, the impact of the NIH and the NCI on drug development programs, and the role of the biotechnology and pharmaceutical industry in clinical cancer research.

This course is designed to provide physicians and others involved in developing and managing clinical trials with key information to advance a program of clinical research, to foster better clinical trial design and ultimately improve patient care.

Course goals are to:

- Discuss the full spectrum of challenges and opportunities in clinical cancer research.
- Facilitate collaborations and diverse networks among workshop participants.
- Provide guidance on the development of clinical trial protocols.
- Introduce principles of good trial design.
- Develop a cadre of well-trained, experienced clinical researchers who will become future leaders in translational cancer research.

TARGET AUDIENCE

This educational activity is intended for physicians in all oncology specialties, including hematology, medical oncology, surgical oncology, radiation oncology, gynecologic oncology, urologic oncology, and pediatric oncology, as well as basic and population science researchers, pharmacists, physician assistants, advanced registered nurse practitioners, nurses, research members, residents, fellows, postdoctoral scholars, and medical and graduate students.

CREDIT DESIGNATION

The University of Miami Leonard M. Miller School of Medicine designates this live activity for a maximum of **18 AMA PRA Category 1 Credits™**. Participants should claim only the credit commensurate with the extent of their participation in the activity.

ACCREDITATION

The University of Miami Leonard M. Miller School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

LEARNING OBJECTIVES

At the conclusion of this activity, participants will be able to:

- Explain the concepts and rationale for phase I, II, III, and non-interventional studies and describe aspects of design and methodology used in each type of study.
- Describe the role of biomarkers in clinical research and apply strategies that incorporate biomarkers into study design.
- Assess the potential of high-throughput -omics assays and explain the basics of Next-Gen Sequencing.
- Appraise the value of correlative studies in clinical research.
- Illustrate how collaborations can lead to the most impactful science, clinical translational studies, and new clinical management paradigms.
- Distinguish between clinical practice and clinical research, including how ethical principles differ.
- Summarize federal regulatory requirements regarding clinical trials and the responsibilities of an investigator.
- Identify common FDA application types for drugs, devices, and biologics.
- Describe the types of committees involved in the protocol approval process and discuss aspects of protocol budgeting, contracting, etc.
- Differentiate the roles of members of the clinical research team.
- Compare the potential career paths of clinical trialists and identify sources of support best suited to their research interests and career stage.
- Describe key factors in determining patentability of an innovation and whether patenting is the only path to commercialization.
- Identify factors that contribute to cancer health disparities in the U.S. and globally.
- Explain the pillars of valid consent and describe some of the origins of current research ethics standards.
- Recognize the roles and value of incorporating PROs into clinical research and clinical practice.
- Evaluate how the increasingly competitive landscape of drug development impacts clinical trial design and endpoints.

DISCLOSURE AND CONFLICT OF INTEREST RESOLUTION

All conflicts of interest of any individual(s) in a position to control the content of this CME activity will be identified and resolved prior to this educational activity being provided. Disclosure about provider and faculty relationships, or the lack thereof, will be provided to learners.

ZOOM INFORMATION

This course will be conducted entirely online via Zoom. Zoom login details will be included in the registration confirmation email.

Register here:
cvent.me/Bd4kqV

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Alan Pollack, M.D., Ph.D.
Professor and Chair of Radiation Oncology
PI, Sylvester K12 Calabresi Clinical Oncology Research Career Development Program

Vaughn Edelson, MP.H., M.P.A.
Sr. Project Manager, Education & Training

GUEST FACULTY

Brandy Heckman-Stoddard, Ph.D., M.P.H.
Chief, Breast and Gynecologic Cancer Research Group
Division of Cancer Prevention, National Cancer Institute
National Institutes of Health

Alexia Iasonos, Ph.D.
Attending Biostatistician
Memorial Sloan Kettering Cancer Center

Quynh-Thu Le, M.D.
Katharine Dexter McCormick & Stanley McCormick Memorial Professor
Professor and Chair of Radiation Oncology
Stanford University

Camille C. R. Ragin, Ph.D., M.P.H.
Associate Director for Diversity, Equity, Inclusion, and Accessibility
Professor, Cancer Prevention and Control Program
Fox Chase Cancer Center

Mirat Shah, M.D., M.H.S.
Medical Oncologist
U.S. Food and Drug Administration

Shuang (George) Zhao, M.D.
Assistant Professor of Human Oncology
University of Wisconsin School of Medicine and Public Health

UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE / SYLVESTER COMPREHENSIVE CANCER CENTER FACULTY

Matthew Abramowitz, M.D.
Associate Professor of Radiation Oncology
Co-Chair, Protocol Review and Monitoring Committee

Juan Alderuccio, M.D.
Associate Professor of Medicine

Marijo Bilusic, M.D., Ph.D.
Professor of Medicine

Vivienne Carrasco, M.P.H.
IRB Associate Director of Regulatory Affairs, Human Subjects Research Office

Macarena de la Fuente, M.D.
Associate Professor of Neurology
Chief, Division of Neuro-Oncology, and Neuro-Oncology Clinical Service Leader

Gilberto de Lima Lopes, M.D., M.B.A.
Professor and Chief, Division of Medical Oncology
Associate Director, Global Oncology
Medical Director, International Programs

Kenneth Goodman, Ph.D.
Professor of Medicine, Philosophy, Health Informatics, Public Health Sciences, Electrical & Computer Engineering, Anesthesiology, Nursing & Health Studies
Founder and Director, Institute for Bioethics and Health Policy

Whitney Hough, Ph.D., M.B.A.
Director of Technology Transfer

Dickran Kazandjian, M.D.
Professor of Medicine

Norma Sue Kenyon, Ph.D.
Martin Kleiman Professor of Surgery, Microbiology & Immunology, Biomedical Engineering, Biochemistry & Molecular Biology
Chief Innovation Officer
Vice Provost, Innovation

Susan Kesmodel, M.D.
Professor of Surgery
Director of Breast Surgical Oncology
Medical Director, Operating Room

Jose Lutzky, M.D.
Professor of Clinical Medicine
Director, Cutaneous Oncology
Leader, Cutaneous and Ocular Oncology Site Disease Group
Medical Director, Clinical Trials Office

Jaime Merchan, M.D., M.M.Sc.
Professor of Medicine
Director, Phase I Program

Craig Moskowitz, M.D.
Professor of Medicine
Physician-in-Chief, Oncology Service Line

Frank Penedo, Ph.D.
Professor of Psychology
Associate Director, Cancer Survivorship and Translational Behavioral Sciences
Director, Cancer Survivorship and Supportive Care
Program Co-Leader, Cancer Control Research Program

Estelamari Rodriguez, M.D.
Staff Physician
Assistant Director for Diversity, Equity, and Inclusion

Mikkael Sekeres, M.D.
Professor and Chief, Division of Hematology

Nima Sharifi, M.D.
Scientific Director, Desai Sethi Urology Institute

Jonathan Trent, M.D., Ph.D.
Professor of Medicine
Associate Director for Clinical Research
Director, Bone and Soft-Tissue Sarcoma Site Disease Group
Co-Director, Musculoskeletal Center, Sarcoma Medical Research Program

Scott Welford, Ph.D.
Professor of Radiation Oncology
Associate Director for Faculty Development

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AGENDA*

FRIDAY, SEPTEMBER 8, 2023

10:00 a.m. - 10:05 a.m. Welcome and opening remarks
Alan Pollack, M.D., Ph.D.

10:05 a.m. - 11:15 a.m. Phase I clinical trial design and statistics
Jose Lutzky, M.D., and Alexia Iasonos, Ph.D.

11:15 a.m. - 12:30 p.m. Phase II clinical trial design and statistics
Jonathan Trent, M.D., Ph.D., and
Alexia Iasonos, Ph.D.

12:30 p.m. - 1:00 p.m. Panel: MD-PhD collaborations in clinical research
Jose Lutzky, M.D.,
Nima Sharifi, M.D.,
Jonathan Trent, M.D., Ph.D.,
Scott Welford, Ph.D

FRIDAY, SEPTEMBER 15, 2023

10:00 a.m. - 11:15 a.m. Phase III and non-interventional trial design and statistics
Quynh-Thu Le, M.D., Ph.D., and
Alexia Iasonos, Ph.D.

11:15 a.m. - 12:15 p.m. Genomic ancestry and head and neck cancer
Camille C. R. Ragin, Ph.D., M.P.H.

12:15 p.m. - 1:00 p.m. Case study: Diversity, recruitment, and retention in clinical trials
Estelamari Rodriguez, M.D.

FRIDAY, SEPTEMBER 22, 2023

10:00 a.m. - 11:00 a.m. Case study: Clinical trial ethics and valid consent
Kenneth Goodman, Ph.D.

11:00 a.m. - 11:45 a.m. Patient-reported outcomes in clinical research
Frank Penedo, Ph.D.

11:45 a.m. - 12:30 p.m. What it measn to be a PI
Marijo Bilusic, M.D., Ph.D.

12:30 p.m. - 1:00 p.m. Panel: Being a sponsor
Matthew Abramowitz, M.D.,
Marijo Bilusic, M.D., Ph.D.,
Susan Kesmodel, M.D.

FRIDAY, SEPTEMBER 29, 2023

10:00 a.m. - 10:45 a.m. Considerations in special trial design
Gilberto de Lima Lopes, M.D., M.B.A.

10:45 a.m. - 11:30 a.m. Incorporating biomarkers into your clinical trial
Jaime Merchan, M.D., M.M.Sc.

11:30 a.m. - 12:15 p.m. Bioinformatics for biomarkers in clinical trials
Shuang (George) Zhao, M.D.

12:15 p.m. - 1:00 p.m. Panel: Correlative studies
Gilberto de Lima Lopes, M.D., M.B.A.,
Jaime Merchan, M.D., M.M.Sc.,
Shuang (George) Zhao, M.D.

FRIDAY, OCTOBER 6, 2023

10:00 a.m. - 11:00 a.m. The road to regulatory approval
Mikkael Sekeres, M.D.

11:00 a.m. - 11:45 a.m. Interacting with the FDA
Mirat Shah, M.D., M.H.S.

11:45 a.m. - 12:30 p.m. Case study: Accrual and feasibility for ISTs - Practical matters, pearls, and an FDA perspective from the other side
Dickran Kazandjian, M.D.

12:30 p.m. - 1:00 p.m. Panel: The IRB and the FDA
Vivenne Carrasco, M.P.H.,
Dickran Kazandjian, M.D.,
Mikkael Sekeres, M.D.,
Mirat Shah, M.D., M.H.S.

FRIDAY, OCTOBER 13, 2023

10:00 a.m. - 10:45 a.m. Innovation and the path to patenting
Whitney Hough, Ph.D., M.B.A., and
Norma Sue Kenyon, Ph.D.

10:45 a.m. - 11:30 a.m. NCI clinical trial funding mechanisms
Brandy Heckman-Stoddard, Ph.D., M.P.H.

11:30 a.m. - 12:15 p.m. Crafting a successful LOI
Macarena de la Fuente, M.D.

12:15 p.m. - 1:00 p.m. Panel: Maximizing productivity in clinical studies
Juan Alderuccio, M.D.,
Macarena de la Fuente, M.D.,
Craig Moskowitz, M.D.

**All times are in Eastern Daylight Time.*