2026 DESIGN AND MANAGEMENT OF CANCER CLINICAL TRIALS COURSE

AUGUST 28: Pre-course workshop, "Clinical Trial Fundamentals: From Protocol to Practice"

FRIDAY, SEPTEMBER 11
FRIDAY, SEPTEMBER 18
FRIDAY, SEPTEMBER 25
FRIDAY, OCTOBER 2
FRIDAY, OCTOBER 9
FRIDAY, OCTOBER 16

OCTOBER 30: Workshop presented by the Miami Herbert School of Business, "AI in Clinical Research: A Leader's Guide to Strategy and Governance"

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

- Phase I, II, III, and non-interventional trial design and statistics
- Responsibilities of a PI
- Biomarkers, bioinformatics, and correlative studies
- Federal regulatory processes and funding mechanisms
- Ethical issues in clinical research, including AI
- Patient-reported outcomes in clinical trials
- Case studies highlighting issues related to recruitment and retention, community engagement, and the use of technology in clinical trials

PROGRAM DIRECTORS

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

Vaughn Edelson, MPH, MPA
Director, Research Support, Sylvester Office of Education and Training

REGISTRATION AND INFORMATION

Sylvester.org/ClinicalTrialsCourse

Presented by:

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM
NCI Designated Cancer Center

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 clinically focused cancer research.

TARGET AUDIENCE

We believe clinical research education works best when people learn together—not in silos. 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.

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.

The University of Miami School of Nursing and Health Studies is an accredited provider of continuing nursing professional education by the American Nurses Credentialing Center's (ANCC) Commission on Accreditation.

CREDIT DESIGNATION

Physicians: The University of Miami Leonard M. Miller School of Medicine designates this live activity for a maximum of 19.75 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in activity.

Nurses: The University of Miami School of Nursing and Health Studies designates this live activity to award a maximum of 19.75 *Continuing Nursing Education contact hours*. Nurses should claim only the credit commensurate with the extent of their participation in activity.

LEARNING OUTCOMES

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

- Explain the concepts, rationale, key characteristics and differences for phase I, II, and III clinical trials and describe aspects of design and methodology used in each type of study.
- Describe the role of biomarkers in clinical research and apply strategies to incorporate biomarkers into study design.
- Review the value of correlative studies in clinical research.
- Discuss the differences 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.
- Name the committees involved in the protocol approval process and discuss aspects of protocol budgeting, contracting, etc.
- Discuss the roles of different members of the clinical research team.
- Explain how AI, including machine learning and natural language processing, can be used to analyze patient data to identify eligible candidates for trials.
- Recognize the roles and value of incorporating patient-reported outcomes into clinical research and clinical practice.
- Formulate a plan to promote community engagement in their next clinical trial.
- Discuss 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 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.

COURSE ACCESS

This course will be conducted entirely online. Login details will be included in the registration confirmation email.

Register here:
Sylvester.org/ClinicalTrialsCourse

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PROGRAM DIRECTORS

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GUEST FACULTY

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Vice President for Health Promotion

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Associate Professor of Business Technology and Health Management & Policy

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AGENDA

All times are in Eastern Daylight Time (UTC -4)

FRIDAY, AUGUST 28, 2026

Special pre-course workshop

10:00 – 12:00 p.m. **Fundamentals of Clinical Research: From Protocol to Practice**
Lucia Carranza, MSN, APRN, AOCNP

A comprehensive introduction to clinical research, covering key topics such as trial phases, patient enrollment and informed consent, research documentation, and protocol navigation. Designed for nurses and advanced practice providers but open to all clinical research professionals, the workshop will equip participants with practical knowledge and skills to engage in and support clinical studies and will serve as a primer for the rest of the course.

FRIDAY, SEPTEMBER 11, 2026

10:00 – 10:15 a.m. **Welcome and opening remarks**
Alan Pollack, M.D., Ph.D.,
and Vaughn Edelson, MPH, MPA

10:15 – 11:40 a.m. **Phase I clinical trial design and statistics**
Jose Lutzky, M.D., and Cody Chiuzan, Ph.D.

11:40 a.m. – 1:00 p.m. **Phase II clinical trial design and statistics**
Macarena de la Fuente, M.D.,
and Alexia Iasonos, Ph.D.

FRIDAY, SEPTEMBER 18, 2026

10:00 – 11:25 a.m. **Design of phase III therapeutic oncology trials and beyond**
Mitchell Machtay, M.D.,
and Chen Hu, Ph.D., M.S.

11:25 a.m. – 12:15 p.m. **Special considerations for precision medicine in lung cancer**
Barb Melosky, M.D.

12:15 – 1:00 p.m. **What it means to be a PI**
Marijo Bilusic, M.D., Ph.D.

FRIDAY, SEPTEMBER 25, 2026

10:00 – 10:50 a.m. **Crafting a successful LOI**
Juan Alderuccio, M.D.

10:50 – 11:40 a.m. **Incorporating biomarkers into your clinical trials**
Jessica Geiger, M.D.

11:40 a.m. – 12:10 p.m. **Networking break**

12:10 – 1:00 p.m. *Special keynote presentation:*
Bioinformatics and liquid biopsies in contemporary clinical trials
Razelle Kurzrock, M.D.
Non-CME session / Non-CNE session

CONCURRENT SESSION

Special topics for clinical research professionals

SEPTEMBER 25, 2026

10:00 – 11:00 a.m. **The clinical research team in action: Working together for trial success**
Jaime Merchan, M.D., MMSc, Leah Anton, APRN, Stephanie Baboun, B.S. CCRP, Esperanza Bas, Ph.D., Giselle Marie Izquierdo, MSN, R.N., Ally Walker, BSN, R.N.

11:00 a.m. – 12:00 p.m. **More than a signature: The informed consent process**
Cynthia Beaver, MPH, CCRC, Peggy Gonzalez, Ms.Ed., Aida Margarita Van Mossel, MPH

12:00 – 1:00 p.m. **Getting it right the first time: Regulatory submissions and IRB review**
Di Ding, Ph.D., Stephanie Dunkle, MBA, CIP, Jose Garcia, MBA

FRIDAY, OCTOBER 2, 2026

10:00 – 10:55 a.m. **Protocol approval from start to finish**
Craig Moskowitz, M.D.

10:55 – 11:45 a.m. **Building trust in clinical trials**
Estelamari Rodriguez, M.D., MPH

11:45 a.m. – 12:30 p.m. **Patient-reported outcomes in clinical trials**
Frank Penedo, Ph.D.

12:30 – 1:00 p.m. **Panel: Clinical trial funding mechanisms**
Christina Annunziata, M.D., Ph.D.,
C. Ola Landgren, M.D., Ph.D.,
Goli Samimi, Ph.D., MPH

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AGENDA (CONTINUED)

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CONCURRENT SESSION

Special topics for nurses and advanced practice providers, in collaboration with the Oncology Nursing Society

OCTOBER 2, 2026

10:00 – 10:05 a.m.	**Welcome** Erica Fischer-Cartlidge, DNP, CNS, AOCNS, EBP-C
10:05 – 10:35 a.m.	**Clinical Research Nursing: Role, Evolution, and the Future** RuthAnn Gordon, MSN, R.N., FNP, OCN
10:35 – 11:25 a.m.	**Frontline voices: Orientation and early-career success** Carrie Burgess, BSN, R.N., OCN, CCRP, Viola Chitiyo, BSN, R.N., OCN, Marisa Maroccia, MBA, BSN, R.N., Asia McCoy, MSN-CRN, RN, OCN, Leslie Paz, MSN, R.N., OCN, CCRC
11:25 – 11:35 a.m.	**Break**
11:35 a.m. – 12:05 p.m.	**Optimizing the patient experience in early-phase clinical trials** Debra Lundquist, Ph.D., R.N.
12:05 – 12:55 p.m.	**Optimizing the role of the clinical research nurse in critical trial timepoints** Andrea Hansen, PhD, RN, ACNS-BC, OCN, Adriana Martinez, BSN, R.N., Doris Stocker, MSN, RN, OCN
12:55 – 1:00 p.m.	**Closing, reflections, and call to action** Jessica MacIntyre, DNP, MBA, APRN, AOCNP

FRIDAY, OCTOBER 9, 2026

10:00 – 10:55 a.m.	**The road to regulatory approval** Mikkael Sekeres, M.D., M.S.
10:55 a.m. – 12:05 p.m.	**Interacting with the FDA** Mirat Shah, M.D., MHS, and Emily Baldwin, B.A.
12:05 – 1:00 p.m.	**International clinical trial infrastructure** Marcia Cruz Correa, M.D., Ph.D., Giuseppe Carlo Iorio, M.D., Paul Keall, Ph.D.

CONCURRENT SESSION

An immersive experience in the clinical trials and tribulations of obtaining FDA approval of new treatments.

OCTOBER 9, 2026

10:00 a.m. – 1:00 p.m.	**Dungeons and drug approvals** Sarah Chadwell, M.S., CGC, Leanne Hagen, M.S., CGC, Farrah Jackson, M.S., CCRP, Carolyn Raski, M.S., CGC

Using a mix of knowledge and chance, this interactive game allows players to explore the clinical trials process from the viewpoint of several members of the clinical research team: PI, sponsor, pharmacist, regulatory specialist, and clinical trials coordinator.

FRIDAY, OCTOBER 16, 2026

10:00 – 10:50 a.m.	**AI deployment in clinical trials in oncology** Iskandar Haykel, M.A.
10:50 – 11:35 a.m.	**How oncologists and patients with cancer view AI tools in clinical research** Andrew Hantel, M.D.
11:35 a.m. – 12:15 p.m.	**Building U-ACCESS: A case study and lessons learned in AI-driven clinical trial matching** Brandon Palmisano, MBA
12:15 – 1:00 p.m.	**The ethics of AI in clinical research** Louis Voigt, M.D.

CONCURRENT SESSION

An interactive session highlighting foundational principles, participatory methods, and real-world case studies of community engagement in clinical research.

OCTOBER 16, 2026

10:00 a.m. – 1:00 p.m.	**Community-engaged research in cancer clinical trials** Erin Kobetz, Ph.D., MPH, and Denise Vidot, Ph.D., with Tiffany Albury, MPH, Alicia Diaz Oria, MPH, Bria-Necole Diggs, MPH, Lisa Quammie-John, MPH, Sandy Rosende, B.S.

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AGENDA (CONTINUED)

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FRIDAY, OCTOBER 30, 2026

New post-course workshop, in collaboration with the University of Miami Business School
Paid session: $699, 10% early-bird discount through August 28
Non-CME session / Non-CNE session

10:00 a.m. – 1:00 p.m. **AI in Clinical Research: A Leader's Guide to Strategy and Governance**
Niam Yaraghi, Ph.D., Philip Arlen, Ph.D., Stephan Schürer, Ph.D.

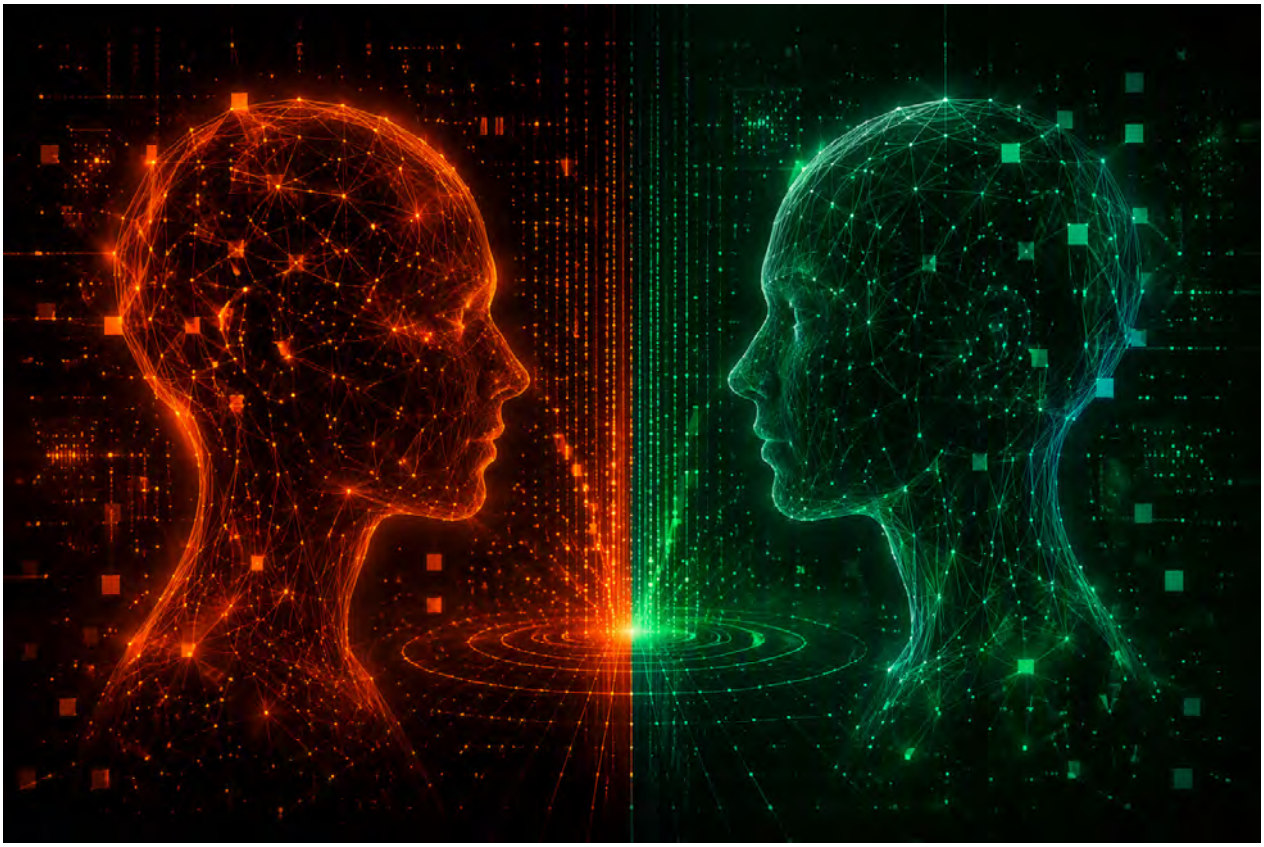
A small-group session examining the business and strategic implications of AI in clinical research, with a focus on the decisions research leaders, healthcare executives, and industry partners will need to make as AI becomes increasingly embedded in clinical trial operations. Rather than focusing on technical development, the session takes a leadership and implementation lens.

Module 1: Deciding what's worth doing. Where is AI creating real value in clinical trial operations today? Through a live case study, participants tackle a build, buy, or partner decision facing a cancer center research office and apply a practical decision matrix they can use in their own organizations.

Module 2: Governance, risk, and why pilots stall. Participants explore the five questions every leader should ask before adopting an AI tool, evaluate a real-world vendor pitch, and examine lessons from two decades of health IT implementation research. Each participant assesses an initiative from their own organization using a ten-item readiness framework.

Module 3: From the front lines. A working conversation with leaders at Sylvester/University of Miami on what AI implementation in clinical research looks like in practice. Participants receive live feedback on their own projects and gain insights from real-world successes, challenges, and lessons learned.

Dr. Yaraghi, of the University of Miami Business School and the Brookings Institution, brings both academic research and hands-on experience building AI-enabled tools in healthcare. Participants will leave with a practical playbook for driving responsible, high-value AI adoption across their organizations.



Questions? SylvesterCTC@miami.edu