Clinical Research Education Series: Operations, Regulatory and Quality

Clinical Research Education Series: Operations, Regulatory and Quality Assurance Applications 2025-2026 - 11/13/2025 Compliance Practices of the ACC November 13, 2025 8:00 AM - 9:00 AM

Target Audience

This program has been designed for INTERNAL MEDICINE - Hematology, INTERNAL MEDICINE - Medical Oncology

Series Educational Objectives

After participating in this regularly scheduled series, participants should be able to:

- 1 Discuss knowledge, skills/strategies, and competencies of research team members
- 1 Discuss how to contribute to positive changes in behavior and improvement in the professional performance of research team members
- 2 Discuss preexisting research skills and knowledge
- 3 Describe interdisciplinary research practice, collaboration, and communication within the research team and with collaborating departments

Session Educational Objectives

After completing this educational activity, participants should be able to:

- 1 Describe the internal research protocol auditing practices of the ACC DOCM and ACC internal auditing practices in alignment with the NCI-approved institutional DSMP.
- 2 Review the Abramson Cancer Center Data Safety Monitoring Plan (DSMP), including preparation strategies for internal and external audits, and lessons learned from past external audits.
- 3 Discuss the differences in auditing requirements based on the DSMC risk category assigned at the time of CTSRMC review.

Accreditation

In support of improving patient care, Penn Medicine is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Designation of Credit

Physicians: Penn Medicine designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)* $^{\text{TM}}$. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses: This activity is for **1.00** contact hours.

Pharmacists: This activity is approved for **1.00** contact hours

UAN Number: JA0000324-0000-25-004-L04-P

PAs: Penn Medicine has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria.

For more information, please contact Rianne Cueto, Mark Harper (267) 357-1594, (215) 220-9663

Rianne.Cueto@pennmedicine.upenn.edu, mark.harper@pennmedicine.upenn.edu

Check your transcript online at https://upenn.cloud-cme.com

This activity is designated for **1.00** AAPA Category 1 CME credit(s). PAs should only claim credit commensurate with the extent of their participation.

Acknowledgement of Commercial Support*

None



Disclosure of Relevant Financial Relationships and Unapproved Uses of Products

It is policy at Penn Medicine Office of Continuing Medical and Interprofessional Education for individuals who are in a position to control the content of an educational activity to disclose to the learners all relevant financial relationships(RFRs) that they have with any ineligible company, which is defined as any company whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Disclosure to learners includes all RFRs for all those in control of content including faculty, planners, moderators, and reviewers.

The intent of this policy is to ensure that Penn CME/CE certified activities promote quality and safety, are effective in improving medical practice, are evidence-based, are based on valid content, and are independent of control from ineligible companies and free of commercial bias. Peer review of all content was conducted for all faculty presentations whose disclosure information was found to contain any financial relationships. Part of the peer review process involved reviewing the content, determining which financial relationships were relevant, and applying appropriate mitigation strategies. In addition, all faculty were instructed to provide balanced, scientifically rigorous and evidence-based presentations.

The staff in the Office of Continuing Medical and Interprofessional Education (CME and IPCE), have disclosed that they have no financial relationships with any ineligible companies. Any peer reviewer who is determined to have a relevant financial relationship must recuse themselves from the peer review process.

Name of individual	Individual's role in activity	Nature of Relationship(s) / Name of Ineligible Company(s)
Dan T. Vogl, MD	Other Planning Committee Member	Consulting Fee-Takeda Pharmaceuticals (Relationship has ended) Consulting Fee-Janssen Pharmaceuticals (J&J) (Relationship has ended) Consulting Fee-Glaxo Smith Kline (Relationship has ended) Consulting Fee-Karyopharm (Relationship has ended) Grant or research support-Takeda Pharmaceuticals (Relationship has ended) Grant or research support-Active Biotech Consulting Fee-CSL Behring (Relationship has ended) Consulting Fee-Sanofi Genzyme (Relationship has ended) Consulting Fee-Genentech (Relationship has ended) Consulting Fee-AbbVie, Inc. (Relationship has ended) Consulting Fee-AbbVie, Inc. (Relationship has ended) Consulting Fee-Bristol-Myers Squibb (Relationship has ended) - 12/12/2024
Maria C Hendricks, MSN	Nurse Planner	Nothing to disclose - 06/11/2025
Rianne Cueto, BSN	Course Director, Other Planning Committee Member	Nothing to disclose - 06/11/2025
Rachel Lundberg, PA-C	Physician Assistant Planner	Nothing to disclose - 06/24/2025
Oxana Megherea, PharmD	Pharmacy Planner	Advisor-BioLineRx (Relationship has ended) - 06/13/2025
Leslie Dyal, BS	Faculty	Nothing to disclose - 10/01/2025

Relevant financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected