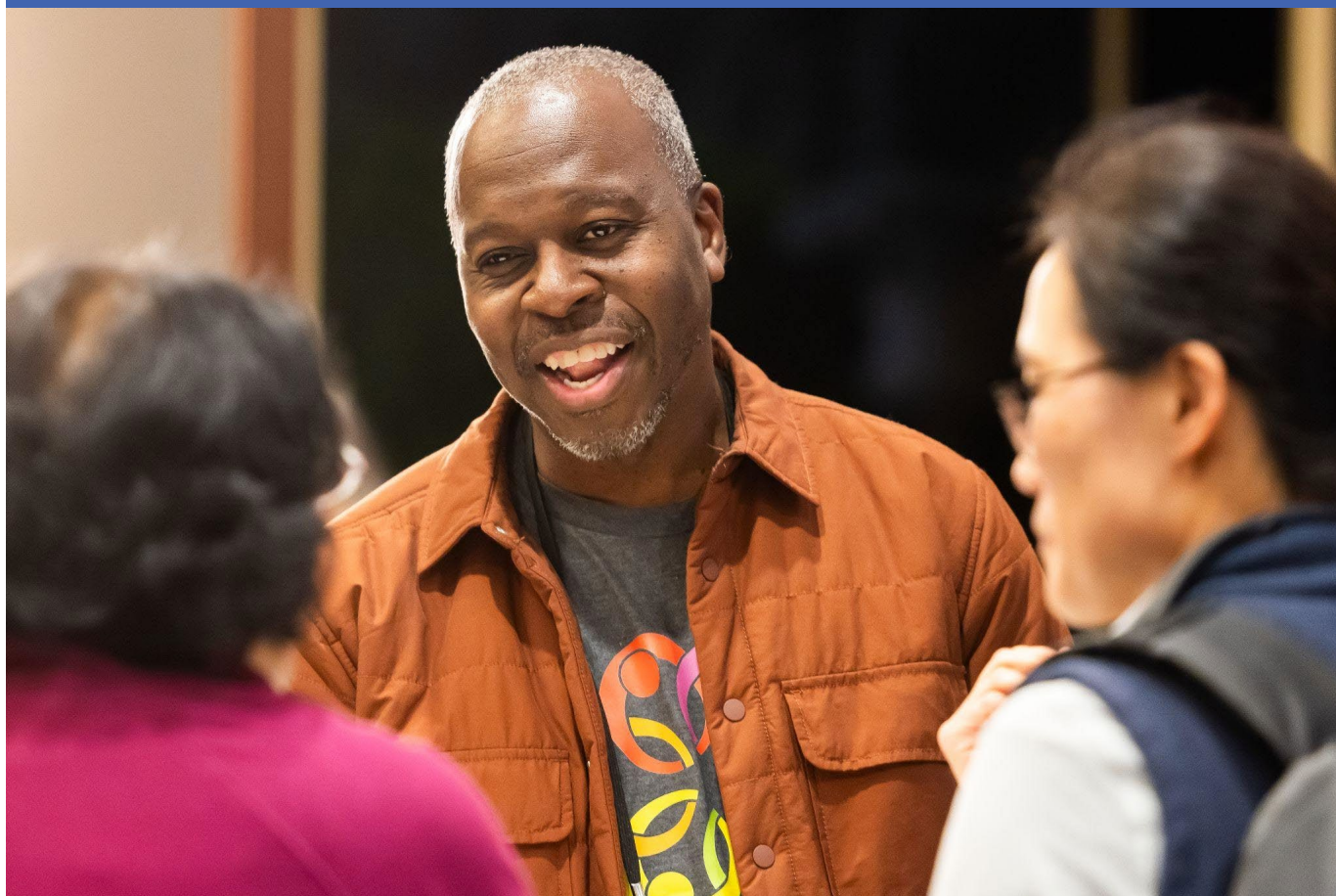




ROBERT A. WINN
DIVERSITY
IN CLINICAL TRIALS
AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation

Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA)



2024 Mentor Handbook

**ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: CAREER
DEVELOPMENT AWARD**

MENTOR HANDBOOK

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SECTION 1

ABOUT THE ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: CAREER DEVELOPMENT AWARD PROGRAM (Winn CDA)

PROGRAM SUMMARY & BACKGROUND

Bristol Myers Squibb Foundation (BMSF) and Virginia Commonwealth University Massey Comprehensive Cancer Center (VCU Massey) have created the Robert A. Winn Diversity in Clinical Trials Award Program to increase the diversity of patients enrolled in clinical trials, and ultimately to improve public health through the development of therapeutics for all populations. The initiative consists of a Career Development Award (Winn CDA) program for early-stage clinical investigators and a Clinical Investigator Pathway Program (Winn CIPP) for medical students. It provides emerging investigators the sponsorship, support, and tools they need to conduct clinical trials that will yield new treatments effective in all populations.

The Winn CDA is a 2-year program designed to support the career development of early-stage investigator physicians (as defined by NIH), who are underrepresented in medicine or who have a demonstrated commitment to increasing diversity in clinical research. The program prepares them to become independent clinical trial investigators who are engaged in advancing health equity through their research and mentoring. The Winn CDA offers a comprehensive and integrated approach to increasing diversity in clinical trials through workforce development and clinical trial site development in underserved communities where underrepresented patients receive care. Additionally, the program will assist program investigators in building capacity and standing up new clinical trials sites in communities with diverse and heavily burdened patient populations.

KEY PROGRAM PARTNERS AND SUPPORTERS



BRISTOL MYERS SQUIBB FOUNDATION

The Bristol-Myers Squibb Foundation (BMSF) is committed to improving the health outcomes of populations disproportionately affected by serious diseases by strengthening healthcare worker capacity, integrating medical care and community-based supportive services, and addressing unmet medical needs. Bristol Myers Squibb, BMSF's sole funder, recognizes the need to take concrete steps to better serve and collaborate with an increasingly diverse US population and underserved communities around the world. This is achieved in part through BMSF, which supports community-based programs that promote cancer awareness, screening, care, and support among high-risk populations. BMSF aspires to be at the center of a vibrant healthcare innovation ecosystem, where academic research centers, biotech and biopharma companies all contribute to continued scientific advancement. The commitment of BMS and BMSF to health equity is affecting real, lasting change.

The Bristol Myers Squibb Foundation (BMSF) is the founding partner and primary funder of the Winn CDA program. BMSF is engaging its partners and other stakeholders to develop, execute, evaluate, and promote this innovative initiative to increase diversity in clinical trials, tapping into the often overlooked but powerful resource of racially and ethnically diverse physicians or other physicians who have a demonstrated commitment to increasing diversity in clinical trials. This \$100 million commitment represents the largest initiative under the Bristol Myers Squibb (BMS) and BMSF 5-year commitment of \$300 million to accelerate and expand health equity and diversity and inclusion.



GILEAD SCIENCES, INC.

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

In April 2021, Gilead Sciences joined as a program supporter with a funding commitment of \$14 million to sponsor a total of 40 Winn CDA and 40 Winn CIPP awards through 2027. The program partners encourage others in the healthcare industry to consider participating as faculty and/or sponsors.



AMGEN

Amgen is a values-based company, deeply rooted in science and innovation to transform new ideas and discoveries into medicines for patients with serious illnesses. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

In January 2023, Amgen joined as a program supporter with a funding commitment of \$8 million to sponsor a total of 18 Winn CDA and 18 Winn CIPP awards through 2027.



VIRGINIA COMMONWEALTH UNIVERSITY MASSEY COMPREHENSIVE CANCER CENTER

As the implementation partner for Winn CDA, Virginia Commonwealth University Massey Comprehensive Cancer Center (VCU Massey) is responsible for many aspects of Winn CDA's design, development, implementation, and management. VCU Massey recruits and secures formal agreements (e.g. memoranda of understanding and letters of agreement) with the different program participants, including National Advisory Committee members, Winn CDA Scholar Mentors, speakers, lecturers, Winn Clinical Investigator Pathway Program (CIPP) Students and stakeholders. VCU Massey is directly responsible for ongoing program monitoring and routine process evaluation and will oversee the external evaluation process including selection of the evaluation partner. VCU Massey manages these critical stakeholder relationships and facilitates linkages between these groups to ensure participants' commitment to the program.

VCU Massey Comprehensive Cancer Center is working toward a future without cancer - one revolutionary idea, one promising therapy, and one life saved at a time. Through innovative research, patient care, education and community engagement, VCU Massey Comprehensive Cancer Center is discovering, developing, delivering, and teaching effective means to prevent, detect, treat, and cure cancer and to making these advancements equally available to all. Founded in 1974, Massey was among the earliest cancer centers designated by the National Cancer Institute (NCI). It is the only cancer center in the Richmond metropolitan region and one of only two NCI-designated Comprehensive Cancer Centers in the state, placing it among the top 4 percent of cancer centers in the country. For more, please visit <https://www.masseycancercenter.org/>.



AMERICAN ASSOCIATION FOR CANCER RESEARCH

The American Association for Cancer Research (AACR) is the first and largest cancer research organization dedicated to accelerating the conquest of cancer. Through its programs and services, AACR fosters research in cancer and related biomedical science; accelerates the dissemination of new research findings among scientists and others dedicated to the conquest of cancer; promotes science education and training; and advances the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world.

The American Association for Cancer Research (AACR), in collaboration with BMSF and VCU Massey, will host a week-long training, the Robert A. Winn Diversity in Clinical Trials: Design and Implementation of Clinical Trials (Winn-AACR DICT) Workshop, that exposes early-stage investigators to the full spectrum of challenges in clinical research—surgery; radiotherapy; immunotherapy; targeted therapy; treatment with conventional and investigational agents and devices; multidisciplinary treatment regimens; multimodality and combination treatments; the integration of biomarkers in clinical trials; and the application of data science, machine learning, and emerging technologies to clinical research and digital health.

OTHER STAKEHOLDERS

NATIONAL ADVISORY COMMITTEE

The Winn Award National Advisory Committee (NAC) was established to provide valuable guidance and direction on program development. Composed of distinguished clinical research experts representing stakeholders across the clinical research landscape, NAC members provide input related to program design and policy, and participate in Scholar recruitment, review, and selection processes; and serve as moderators and contributors to program events.

HEALTH AND HUMAN SERVICES PARTNERS

BMSF and VCU Massey also receive advisory support from partner organizations within the US Department of Health and Human Services (HHS), such as the National Institutes of Health (NIH). The National Cancer Institute, National Center for Advancing Translational Sciences, and other NIH/HHS partners provide valuable insights for the Winn Award program development, serve on review and selection committees, are guest lecturers, and contribute to program events.

WINN CDA SCHOLARS

The goal of the Winn CDA is to develop a new generation of world class clinical investigators dedicated to increasing diversity in clinical trials. We will achieve this goal by providing immersive community-based experiences in clinical trial research over a five-year period to 309 physicians (MD, DO, MD/PhD, DO/PhD) from groups underrepresented in medicine or who have demonstrated their commitment to increasing diversity in clinical research.

Winn CDA Scholars are a distinguished group of physicians selected for this bold new initiative to transform the clinical research landscape. Together we will strengthen partnerships between clinical investigators and communities, increase the diversity of patients enrolled in clinical trials, and enhance the development of therapeutics for all populations. The Winn CDA will

provide Scholars with sponsorship, training, and mentoring to support their development as clinical investigators advancing health equity. Winn CDA Scholars will receive training in investigator-initiated and industry-sponsored clinical trials, and in trauma-informed community outreach and engagement.

WINN CDA MENTORS

Each Winn CDA Scholar will be mentored by a Principal Investigator (PI) at an established clinical trial site and will substantively participate in the PI's active clinical trial. Mentors will engage Scholars in the conduct of existing clinical trials and provide exposure to all aspects of clinical trial administration and implementation. The mentor should plan to provide additional mentoring towards the scholar's career, personal, and professional development, with a particular focus on challenges, opportunities, and strategies for underrepresented in medicine (URiM) researchers. Mentor-Scholar interaction requirements include at least four meetings per month, of which three will be related to clinical trial research related activities.

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS: CLINICAL INVESTIGATOR PATHWAY PROGRAM (WINN CIPP) STUDENTS

As part of the Winn CDA, Scholars will serve as mentors to medical students participating in the Robert A. Winn Diversity in Clinical Trials: Clinical Investigator Pathway Program (Winn CIPP). Winn CIPP is a 6-week intensive and immersive summer service-learning externship designed to expose talented medical students of diverse backgrounds to clinical research in community-based clinical research settings (e.g., community health centers, safety net hospitals, clinical research organizations, etc.). The goal of the Winn CIPP is to build the pathway of community-oriented clinical trialists of diverse backgrounds who are committed to increasing inclusion, equity, and diversity in the conduct of clinical and translational research. Winn CIPP Students will gain exposure to clinical research and acquire community engagement and leadership skills. During their 6-week externships, Winn CIPP students will meet at least 4 times with their Winn CDA Scholar mentors to discuss clinical research career pathways.

SECTION 2

ABOUT WINN CDA MENTORING

Mentorship is a critical aspect of the Winn CDA, because mentoring can have a critical impact on the success of early-career investigators in navigating challenges and obstacles as they pursue clinical research opportunities—particularly when they are from groups underrepresented in medicine. But, generally, scientific mentoring is one of the most important obligations of senior scientists and has several important goals:

- Teaching an approach and methodology for scientific investigation
- Developing a sense of what questions are able to be answered and have significant answers
- Transmitting a history of ideas in a discipline
- Encouraging development of the ability to evaluate critically the quality of one’s own and others’ research
- Providing an ethical framework for the conduct of research
- Enhancing the development of oral and written communication skills
- Facilitating entrance into the research community in the discipline

In fact, to amplify the importance of mentoring in the career development of clinical researchers, the Winn CDA incorporates a tiered mentoring model. Even as Winn CDA Scholars are mentored by senior colleagues in the two-year program, they also gain mentoring experience by serving as mentors to medical students interested in clinical research. Each summer, they will provide career development mentoring to medical students from diverse backgrounds in the 6-week Winn Clinical Research Pathway Program (CIPP).

Tiered Mentoring Model

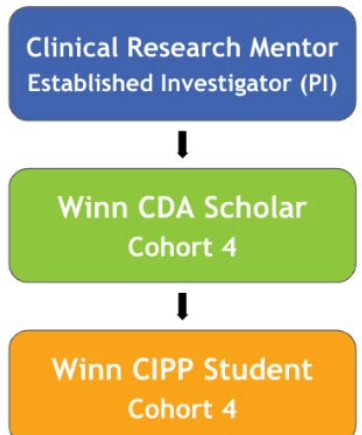


Scholar Mentoring: Scholars are mentored by Principal Investigators (PIs) at established clinical trial sites.



Winn CIPP* Student Mentoring: Scholars mentor URiM medical students.

* Winn Clinical Investigator Pathway Program (Winn CIPP)



WINN CDA MENTORING GUIDELINES

The goals of mentoring in the Winn CDA are:

1. To produce Winn CDA Scholars who possess the knowledge, skills, and competencies of world class clinical trial researchers.
2. To produce a new generation of Community-Oriented Clinical Trialists who possess the knowledge, skills, and competencies to build trust with patient populations underrepresented in medicine and to thereby increase their engagement in clinical trials.

Winn CDA Mentors will achieve these goals by providing career development support and guidance to Winn CDA Scholars as the Scholars assist you in implementing your active clinical trials.

Specifically...

WINN CDA MENTOR ROLE

Provides clinical research experience, support, and guidance to their Winn CDA Scholar for shaping their career in community-oriented clinical research, including:

- Supporting the creation and ongoing development of the Scholar's Individual Professional Development Plan (IPDP)
- Modeling a sustainable career path
- Offering guidance regarding incorporating personal experience into professional life
- Identifying opportunities that may further professional achievement, or barriers that may hinder it, particularly for underrepresented groups

RESPONSIBILITIES OF WINN CDA MENTOR

During the Winn CDA Scholar's two-year program:

- Schedule and complete a minimum of four interactions per month with assigned Winn CDA Scholar, three of which shall be meetings related to clinical trial research activities.
- Commit to Scholar mentoring in the following areas:
 - 75% to clinical trial research mentoring, that engages the Scholar in the conduct of an existing clinical trial and provides exposure to all aspects of CT administration and implementation.
 - 25% to career (e.g., personal and professional) development mentoring, with a particular focus on challenges, opportunities, and strategies for researchers underrepresented in medicine.
- Support the creation and ongoing development of the Scholar's Individual Professional Development Plan (IPDP).

In addition, Winn CDA Mentors participate in Winn CDA program monitoring and evaluation activities, including completion of surveys and interviews with program evaluators.

THE MENTOR/MENTEE RELATIONSHIP

Within the first month of the program, the Mentor and Scholar will develop and submit the Scholar's Individual Professional Development Plan ([Appendix A](#)), which is both their training and career development roadmap for the two-year program and beyond, and their monitoring and outcomes tracking record.

In your first four meetings, please be sure to discuss:

- Your mutual goals for mentoring
- Your personal and professional experiences
- The Scholar's long- and short-term goals for their respective clinical research career paths
- Issues related to underrepresentation in clinical trials
- Career guidance aligned with Scholar's Individual Professional Development Plan (IPDP)

SCHOLAR'S INDIVIDUAL PROFESSIONAL DEVELOPMENT PLAN (IPDP)

Mentors will support their Scholars in developing Individual Professional Development Plans (IPDPs), informed by skills assessments, that will guide the training activities Scholars pursue during the 2-year Winn CDA program. The IPDP will address both clinical research skills (e.g., statistical analysis, biostatistics, etc.) and career/professional development skills (e.g., public speaking, technical report writing, project management, networking). It will thus serve as both the Scholar's training and career development roadmap and their monitoring and outcomes tracking record.

Scholars should begin developing their IPDPs as soon as they begin their program year and review them with mentors during the first or second meeting. The Winn CDA team will schedule virtual IPDP meetings with each Scholar within two months of the program start. The finalized plan will be signed by the Scholar and Mentor within three months of the Scholar's program start. The IPDP will be reviewed biannually and revised as needed.

IPDP TIMELINE

- Scholar creates IPDP: Nov 2024
- Mentor reviews Scholar's IPDP: Nov - Dec 2024 (first or second meeting)
- Winn CDA holds IPDP meetings with each Scholar: Jan-Feb 2025
- Scholar and Mentor sign finalized IPDP: Feb-Mar 2025

- IPDP Review Status Sessions: Jul & Dec 2025, May & Oct 2026

Biannual reviews of the Scholar's progress toward achieving the goals of the IPDP are helpful for both the Mentor and the Scholar to ensure that potential barriers to success are addressed in a timely manner and that the Scholar's career goals are indeed achieved.

SECTION 3

PROGRAM MONITORING AND EVALUATION

Winn CDA Mentors will participate in program monitoring and evaluation activities, as these are critical to understanding how the Winn CDA is working and to measure the program's overall success. Mixed methods will be used to elicit feedback from program stakeholders to monitor and assess different aspects of the program. Routine collection of program data will be used to improve processes and administration and to identify best practices and incorporate lessons learned. Mentors will participate in various evaluation activities including completion of survey questionnaires and individual meetings/interviews.

An external evaluator will be contracted to perform formal program evaluations at the end of cohorts 1, 3, and 5. A final impact evaluation will be conducted 2-years after the final cohort ends in 2029. Mentors will participate in Scholars' program award period.

SECTION 4

MENTOR HONORARIUM

Each Winn CDA Primary Mentor will be paid an honorarium of \$4,800 per year. At the beginning of each program year, Winn CDA will send each Mentor a Memorandum of Understanding (MOU) detailing the roles and responsibilities of the Mentor in supporting the Winn CDA Scholar and in participating in Winn CDA program evaluation activities.

Along with the MOU, Winn CDA will send documents required for disbursement of honoraria. Honoraria will be disbursed annually, at the end of each program year, and are conditioned on the fulfillment of responsibilities specified in the Mentorship Memorandum of Understanding.

Mentors' fulfillment of requirements will be monitored twice annually through Mentor Status Reports (online surveys), one of which will include an Annual Mentorship Assessment. Virtual follow-up meetings with individual Mentors will be scheduled as appropriate.

SECTION 5

MENTOR SUPPORT

Winn CDA will provide both individual and group mentoring support throughout the 2-year Winn CDA. At the beginning of the program, Mentors will participate in a virtual orientation that provides an overview of the Winn CDA and of Mentors' roles and responsibilities. Throughout the program, Winn CDA will share resources on mentoring and invite Mentors to periodic Winn CDA Mentor meetings where they may share experiences, concerns, challenges, and best practices.

SECTION 6

PROGRAM STAFF CONTACTS

Questions or concerns related to the implementation of the program should be directed to:

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SECTION 7

THANKS TO

Winn Awards Partners

FUNDING PARTNERS



IMPLEMENTATION PARTNERS

