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

Informational Webinar

January 19, 2023





## Robert A. Winn Diversity in Clinical Trials Award Program



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

2-yr program for early stage investigators

Robert A. Winn Diversity in Clinical Trials: Clinical Investigator Pathway Program (Winn CIPP)

6-week summer externship URM medical students



## Agenda

#### Welcome and Introduction

Catharine Grimes, MBA: Senior Director, Bristol Myers Squibb Foundation (BMSF)

#### **Program Vision**

Robert A. Winn, MD: Director and Lipman Chair in Oncology, VCU Massey Cancer Center;
 Senior Associate Dean for Cancer Innovation; Professor of Pulmonary Disease and
 Critical Care Medicine, VCU School of Medicine; Chair, Winn Awards National Advisory
 Committee (NAC)

#### **Program Overview**

- Catharine Grimes, MBA
- Joy L. Jones, PhD, Chief Program Officer, Virginia Commonwealth University (VCU)
- Ariana Lee, Program Administrator, American Association for Cancer Research (AACR)



# Bristol Myers Squibb<sup>™</sup> Foundation

Mission: To improve health outcomes and reduce health disparities for underserved populations.

Vision: A world where everyone has equitable access to high quality health care.





Virginia Commonwealth University and its academic health sciences center serve as one national urban public research institution dedicated to the success and well-being of our students, patients, faculty, staff and community through:

- Real-world learning that furthers civic engagement, inquiry, discovery and innovation
- Research that expands the boundaries of new knowledge and creative expression and promotes translational applications to improve the quality of human life
- Interdisciplinary collaborations and community partnerships that advance innovation, enhance cultural and economic vitality, and solve society's most complex challenges
- Health sciences that preserve and restore health for all people, seek the cause and cure of diseases through groundbreaking research and educate those who serve humanity
- Deeply ingrained core values of diversity, inclusion and equity that provide a safe, trusting and supportive environment to explore, create, learn and serve







## BMSF Diversity in Clinical Trials Career Development Program (BMSF DCTCDP)



Robert Winn, MD

Director, Massey Cancer Center Professor, Division of Pulmonary Disease and Critical Care Medicine Virginia Commonwealth University

National Advisory Committee Chair









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

**Catharine Grimes** 

Director, Bristol Myers Squibb Foundation

Joy L. Jones, PhD Chief Program Officer, VCU

Ariana Lee

Program Administrator, AACR





### The Need for Diversity in Clinical Trials

## Definition of Diversity In Clinical Trials

- Engage a patient population that mirrors the epidemiology of the disease studied
- Assure the ecosystem around the trials reflects diverse populations being served. Includes research sites, principal investigators, and extended care teams
- Design in inclusivity from start



## Benefits of Diversity In Clinical Trials

- Better science
   Safety and efficacy of new medicines should be assessed in the patients with the condition
- Personalized medicine
   Understanding the range of different responses to treatments based on genetic variations
- Data
   Better informed treatment decisions by making new options available to patients
- Address disparity and inequity

## Current State of Clinical Trials

- Black Americans represent 13% of the US population but reflect only about 4% of participants in clinical trials
- Hispanics represent 16% of the US population but only about 3% of clinical trial participants
- In general 80% of patients taking part in clinical trials are white\*

\*CDC Heart Disease Facts
https://www.cdc.gov/heartdisease/facts.htm

#### Robert A. Winn Diversity in Clinical Trials: Career Development Award Program

#### Goals



- To transform the clinical research landscape by building and strengthening partnerships between clinical investigators and the communities where their patients reside.
- To facilitate an approach to clinical and translational research that is community-informed, designed and conducted.

#### **Approach**

 Provide training and resources to build a network of URM clinical investigators with community engagement and research skills.

#### Outcome

 Increased participation of diverse patients in clinical and translational research.

#### **Impact**

 Improved public health through an increase in the development of new drugs, vaccines and therapeutic products that are effective in all populations.



## Winn Award Program — Key Program Elements

Commitment	•Bristol Myers Squibb Foundation (BMSF) <sup>1</sup> = \$100M over 5 years •Gilead Sciences, Inc. (Gilead) = \$14MM over 4 years •Train a new generation of 290 community-oriented clinical investigators <sup>2</sup> •Provide early clinical research exposures to 290 URM medical students <sup>2</sup> •Provide opportunities to support ongoing career and leadership development in clinical research  ¹The Winn Award Program was established by BMSF in 2020; ²250 sponsored by BMSF, 40 sponsored by Gilead	
Winn CDA Award	•ESI Physicians: \$240K (\$120K/year for 2 years)	
Training	•Community-Oriented Clinical Trial Design & Implementation •5-day intensive Robert A. Winn Diversity in Clinical Trials: Design and Implementation of Clinical Trials Workshop in partnership with the American Association for Cancer Research (AACR) •Robert A. Winn Diversity in Clinical Trials: 2-year Community-Oriented Clinical Trialist Curriculum, with 43 biweekly lectures by distinguished faculty	
Career Development	•Individual Professional Development Planning  •Mentored career planning and tracking with an experienced Principal Investigator  •Community-Oriented Clinical Trialist Competency Self-Assessment	
Mentoring	•Tiered Mentoring Model •Scholars mentored by Principal Investigators •Scholars will mentor URM medical students each summer (Winn CIPP Students)	
Capacity Building	•Continued Career and Leadership Development Support     •Available to program graduates to support ongoing career and leadership development in clinical research	



## Candidate Eligibility Criteria

Candidate Profile	In determining eligible candidates for the Robert A. Winn Diversity in Clinical Trials: Career Development Award (Winn CDA) program, the following racial/ethnic groups are designated as "underrepresented in medicine":	
Citizenship or Immigration Status	Eligible candidates will be US Citizens or Lawful Permanent Residents (LPRs) as defined by the <u>US Department of Homeland Security</u> NOTE: 0-1 & H-1B Visa holders are eligible; the visa must be valid during the full 2-yr period.	
Professional Degree	Eligible candidates will hold the degree of MD, MD/PhD, DO or DO/PhD	
Career Phase	<u>Early Stage Investigator (ESI):</u> As defined by NIH, a new investigator who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant. (Applicants with an RO1 or RO1 equivalent are ineligible.)	

## Robert A. Winn Diversity in Clinical Trials: Community-Oriented Clinical Trialist Training (Winn COCT Training)

#### Purpose:

To train a new generation of world class clinical trialists who possess the additional knowledge and competencies to foster active community engagement in clinical and translational research.

#### Components:

- → Design and Implementation of Clinical Trials Workshop (5<sup>1/2</sup> days)
- → COCT Curriculum (2-yr)
  - → Scholars Forum
  - → Community Engagement Activities
  - → Capstone Project
  - → Annual Convenings





## Robert A. Winn Diversity in Clinical Trials: Design & Implementation of Clinical Trials Workshop in partnership with the American Association for Cancer Research (AACR) (Winn-AACR DICT Workshop)

#### **Workshop Description**

Exclusive, week-long Workshop that introduces Scholars to foundational knowledge in state-of-theart clinical trial design, development, and implementation. Scholars will meet with small, mentorled development groups throughout the week, receiving valuable guidance in clinical trial protocols and guidance, grant writing and overall professional development.

#### **Program Co-directors**

Roy S. Herbst, Yale University Cancer Center Yu Shyr, Vanderbilt University Medical Center Robert A. Winn, Virginia Commonwealth University Massey Cancer Center











### Winn COCT Training (2 years)

#### Learning Objectives:

- Basic biostatistical and epidemiologic methods
- Principles of patient-oriented research design, management, and monitoring
- Good protocol design
- Good clinical practices (GCPs) for ensuring clinical trial validity
- GCPs related to ethical, legal, and regulatory issues to protect human subjects' safety, rights, and welfare in clinical research
- Infrastructure required for clinical research, and steps involved in developing and funding research studies
- Social and political determinants of health and their impact
- Practices for identifying and evaluating catchment area needs
- Effective, trauma-informed community engagement and partnership building practices

#### **Bi-Weekly Scholar Forums:**

- Duration
  - 2-3 hrs/session
- Formats
  - Virtual webinars/sessions
  - In-person meetings (~ 2/yr.)
  - Community-based interactions (local to Scholars)

#### Features

- Seminars with Subject Matter Experts
- Workshops (e.g., professional skills)
- Roundtables with Community Speakers
- Journal Clubs

NOTE: The 2-YR COCT is being revised and the current structure will change.



### **National Advisory Committee**



Robert Winn MD (Chair)

Director, Massey Cancer Center | Senior Associate Dean for Cancer Innovation | Professor, Division of Pulmonary Disease & Critical Care Medicine, Virginia Commonwealth University



Roy S. Herbst MD. PhD

Ensign Professor of Medicine | Professor of Pharmacology | Chief of Medical Oncology |
Director, Thoracic Oncology Research Program | Associate Director for Translational Research
| Yale Comprehensive Cancer Center | Yale School of Medicine



#### Nancy Daly RN, MS, MPM

Executive Vice President & CEO, Conquer Cancer & the ASCO Foundation



#### Leon Bernal-Mizrachi MD

Associate Professor, Dept of Hematology & Medical Oncology | Service Chief, Hematology & Medical Oncology | Associate Director, Hematology & Medical Oncology | Fellowships Program | Emory University School of Medicine & Grady Health Systems



#### Gail Kerr MD, FRCP

Professor of Medicine & Chief of Rheumatology at Howard University Hospital & Howard University



#### Lori Pierce MD

Professor, Department of Radiation Oncology | Vice Provost for Academic & Faculty Affairs, Michigan Medicine, University of Michigan



#### Edith Mitchell MD, MACP, FCPP

Clinical Professor of Medicine & Medical Oncology | Director, Center to Eliminate Cancer Disparities | Associate Director, Diversity Affairs | Sidney Kimmel Cancer Center at Jefferson Health



#### Karen Winkfield MD, PhD

Executive Director, Meharry-Vanderbilt Alliance, Radiation Oncologist, Vanderbilt University Medical Center



#### Eliseo J. Perez-Stable MD

 ${\it Director, National\ Institute\ on\ Minority\ Health\ \&\ Health\ Disparities\ |\ National\ Institutes\ of\ Health\ |\ Internal\ Medicine\ |}$ 



#### José López MD

Chief Scientific Officer & Full Member | Blood Works Northwest Research Institute | Professor of Medicine, Division of Hematology, University of Washington School of Medicine



#### Lucio Miele MD, PhD

Professor & Dept. Head, LSU School of Med., Dept. of Genetics | Director, Inter-Institutional Programs, LSU Stanley | Scott Cancer Ctr. & Louisiana Cancer Research Consortium | Cancer Crusaders Endowed Professor in Cancer Research | Louisiana State Uni. Health Sciences Ctr.



#### Kathryn Owen Vice President

Head of Global Development Operations Bristol Myers Squibb



#### Ruben Mesa MD, FACP

Presidential Chair, Mays Family Foundation | Distinguished University | Director, Mays Cancer Center | Professor of Medicine. UT Health San Antonio MD Anderson



#### Brian Rivers PhD, MPH

Director, Cancer Health Equity Institute, National Center for Primary Care Morehouse School of Medicine



#### Amelie G. Ramirez DrPH, MPH

Director & Professor, Institute for Health Promotion Research, Graduate School of Biomedical Sciences, UT Health San Antonio | Dept. of Population Health Sciences, Chair | MCC Associate Director for Community Outreach & Engagement



#### Annabelle Volgman MD, FACC, FAHA

McMullan-Eybel Chair of Excellence in Clinical Cardiology | Professor of Medicine, Rush College of Medicine | Medical Director, Rush Heart Center for Women Rush University



#### Winston Wong MD, MS, FAAFP

Scholar-in-Residence, UCLA Kaiser Permanente Center for Equity  $\mid$  UCLA Fielding School of Public Health



#### Hannah Valantine MD

Professor, Cardiovascular Medicine Stanford University Medical Center | Prior: Chief Officer for Scientific Workforce Diversity, National institutes of Health



# How to Apply to the Winn CDA Program

### Desiree Vasquez

Program Manager, Winn CDA





## **Application Process with Key Target Dates**

The full application for Winn CDA Cohort 3 will run from January 3, 2023 through May 12, 2023. The application, which includes all required and supplemental application documents, must be submitted electronically through the Application Portal. The application deadline is May 12, 2023 at 11:59 PM ET. Incomplete applications and late submissions will not be accepted.

Application Process Opens	Jan 3, 2023
Application Closes	May 12, 2023
Selection Process	May 15-Aug 1, 2023
Selection Announcement	Aug 3, 2023
Third Cohort Begins	Oct 2023

Note: Dates are subject to change.



### Cohort 1 - Winn CDA Scholars

## ars Cohort 2 - Winn CDA Scholars



## Winn Award Partners and Supporters

## Bristol Myers Squibb Foundation











## QUESTIONS



# Thank you for your interest in the Robert A. Winn Diversity in Clinical Trials: Career Development Award!

Direct inquiries to: winncda@vcu.edu

Program website: <a href="https://diversityinclinicaltrials.org/">https://diversityinclinicaltrials.org/</a>

