MMRF Second Annual Summit: Improving Equity and Inclusivity in Multiple Myeloma Clinical Research

October 16-17, 2023 | Hyattsville, Maryland

For many patients with multiple myeloma, clinical trials offer the best treatment options. However, not all multiple myeloma patients have equal opportunity to benefit from potentially efficacious therapies under study in clinical trials. Certain populations, including patients who are older, who are Black and/or Hispanic, and/or who live in rural areas, are often excluded from cancer clinical trials. These disparities in access to clinical trials can greatly affect patient outcomes.

As part of the MMRF's commitment to improving health outcomes for all multiple myeloma patients, the Foundation convened the second annual Health Equity Summit to improve equity and inclusivity in multiple myeloma clinical research, held October 16-17, 2023, in Hyattsville, Maryland. The Summit brought together policymakers, academic researchers, biopharma executives, retail pharmacists, and community health advocates to explore strategies and solutions to drive proportional patient representation in clinical research studies.

BUILDING ON THE 2022 HEALTH EQUITY SUMMIT

Since the inaugural Summit in 2022, the MMRF has made significant strides toward increased inclusivity and access to clinical trials. Most notably, the Foundation has appointed an outside Diversity Officer and has committed to implementing a diversity plan for the MMRF HORIZON platform trial (NCT06171685); formed a task force to guide messaging and outreach to engage underrepresented populations; and established the MMRF Scholars program, which supports Black researchers and clinicians pursuing a career in the field of myeloma.

The 2022 Summit inspired advancements toward health equity from other attendees as well, including Ochsner Health and Bristol Myers Squibb (BMS), who reported on efforts to strengthen relationships with community organizations and invest in technologies and digital capabilities to expand site capacity. As a result of these efforts, 36% of Ochsner trial participants are from minority populations (exceeding their goal of 30%), and 38% of BMS U.S. trial sites are now in racially diverse areas (exceeding their goal of 25%).

EXPANDING CLINICAL TRIAL ELIGIBILITY CRITERIA TO INCREASE REPRESENTATION AND INCLUSIVITY

Continuing the conversation in 2023, Hearn Jay Cho, MD, PhD (MMRF), Monique Hartley-Brown, MD (Dana-Farber Cancer Institute/DFCI), and Bindu Kanapuru, MD (U.S. Food and Drug Administration/FDA), led a session focused on reevaluating and expanding cancer clinical trial eligibility criteria—a well-documented factor in the exclusion of racial and ethnic minority groups from cancer clinical trials, including those studying multiple myeloma treatments.

Chief among these exclusionary eligibility criteria are blood count criteria that do not consider racial and ethnic variations. It is well documented that "normal" absolute neutrophil counts (ANC) may be lower among Black patients than White patients, and that Black patients have higher rates of anemia than White patients. Research led by Maureen Achebe, MD, and Lauren Merz, MD (DCFI), shows how benign laboratory differences disproportionately exclude Black patients from clinical trials, given that a quarter of Duffy-null patients (the majority phenotype among Black individuals) have an ANC below the lower limit of "normal." In response to these findings, the MMRF has committed to Duffy status testing for all future MMRF-led clinical trials.

The NCI's Pragmatica-Lung Study is a model for removing barriers that prevent people from joining clinical trials. In addition to its unusually broad eligibility criteria—none, beyond a diagnosis of Stage 4 lung cancer—the Pragmatica-Lung Study is enrolling patients at community clinics as well as academic medical centers. The Study adopted NCI Cancer Therapy Evaluation Program's Generic Protocol Template, which leverages ASCO and FOCR's recommendations for broadening cancer clinical trial eligibility, as well as the FDA's guidance on enhancing diversity in clinical trial populations.

Efforts to improve equitable representation of racial and ethnic minorities are underway in the private sector as well. In an ongoing Phase 4 study of Ninlaro (ixazomib), Revlimid (lenalidomide) and dexamethasone (IRD) in newly diagnosed multiple myeloma patients, Takeda used relaxed eligibility criteria and limited enrollment to community oncology clinics—including several Veterans Administration (VA) centers—where the majority of multiple myeloma patients are treated. As a result, the trial has enrolled approximately 40% of patients who would otherwise not have been eligible if Takeda had used standard inclusion/exclusion criteria and solely enrolled patients from large, academic cancer centers.

EXPANDING ACCESS TO CANCER CLINICAL TRIALS

A second session, led by Ola Banjo, PharmD, (MMRF), Gurbakhash Kaur, MD, (UT Southwestern Medical Center/UTSW), and Brian Rivers, PhD (Morehouse School of Medicine) highlighted several initiatives that have expanded access to clinical trials, including various partnerships that have facilitated the integration of research into the care continuum, and decentralized and hybrid study designs that make clinical trial participation more accessible to diverse and/or underrepresented populations.

One example is a research collaboration between Emory University's Winship Cancer Center and Grady Memorial Hospital, a large, public safety-net hospital serving predominantly Black, uninsured or Medicaid-covered patients living in metro Atlanta. Through this longstanding collaboration, patients at Grady can access treatments under study in Winship clinical research, and Winship investigators are able to consistently enroll a racially diverse population into their clinical trials.

The VA's Cooperative Studies Program (CSP) also serves as an exemplar for integrating research into the point of care while as well as decentralized trial design. By embedding clinical research into clinical care, the CSP is now enrolling veterans into clinical trials at 85 of every 100 VA centers nationwide. As evidence of their commitment to "bringing clinical trials to veterans, rather than bringing veterans to clinical trials," study coordinators on the MATCH clinical trial flew to patients' homes to enroll them. Following the emergence of COVID-19, this also included enrolling patients via video.

UTSW's Simmons Cancer Center's clinical trial navigator program demonstrates yet another approach to increasing representation in clinical trials. Linguistic and culturally appropriate clinical trial navigators help patients from racial and ethnic minorities understand the importance and benefits of clinical trials through patient education, community outreach, and language support. UTSW cited one trial in which navigators provided bilingual support and saw the enrollment rate increase by 110%.

ADDRESSING FINANCIAL TOXICITY TO INCREASE DIVERSITY IN CLINICAL TRIALS

Cost is a decisive deterrent for many patients from underrepresented groups, and addressing financial toxicities is a crucial step in achieving clinical trial diversity.

Organizations such as Greenphire help minimize the financial burden of clinical trial participation on patients by streamlining reimbursement and payment and providing travel booking. Similarly, the Lazarex Cancer Foundation provides financial assistance to trials participants, in addition to navigation, advocacy, outreach and community engagement. The MMRF has partnered with Lazarex to improve enrollment and diversity in clinical trials through Lazarex's PATH and CARE programs. This partnership supports patients who are enrolled in any myeloma clinical trial with uncovered financial expenses related to the trial such as transportation or lodging. .

Funding to support community partners is also an important part of addressing equity in clinical trials. The NIH All of Us program directly funds 18 Community Engagement Partners and supports over 150 sub-awardees to help resource diverse participation. 80% of All of Us participants are from communities underrepresented in biomedical research, 50% of whom identify as racial or ethnic minorities.

TURNING INSIGHTS INTO ACTION

Addressing inequities in myeloma clinical research is intrinsic to the MMRF's goal of ensuring every person with multiple myeloma gets optimized treatment, and eventually a cure. The Foundation is taking action to integrate into its research strategy key learnings shared at the Summit.

In 2024, the MMRF will begin enrollment in the HORIZON Clinical Trials Program, which will include expanded inclusion/exclusion criteria and a new adaptive platform model to broaden the eligible patient population. HORIZON will use a hub and spoke model, offering the option to add community sites throughout the course of the trial, and will leverage remote monitoring to reduce both patient and site burden. In the meantime, the MMRF is piloting programs at clinical trial sites where navigators and/or community health workers are engaged to support the community and build the concept of clinical trials.

Results from HORIZON trials will enable researchers to identify the best combinations of therapies as well as the optimal duration and sequencing for diverse patient populations with unmet needs.

APPENDIX 1: List of Attendees

Co-Chairs

Ola Banjo, PharmD, AAHIVP
Senior Director, Community Engagement and Partnerships
Multiple Myeloma Research Foundation

Hearn Jay Cho, MD, PhD
Chief Medical Officer
Multiple Myeloma Research Foundation

Anne Quinn Young, MPH
Chief Mission Officer
Multiple Myeloma Research Foundation

Session Chairs

Monique Hartley-Brown, MD, MMSc
Medical Oncology
Dana-Farber Cancer Institute

Bindu Kanapuru, MD
Multiple Myeloma Team Lead, Division of Hematologic Malignancies 2
US Food and Drug Administration

Gurbakhash Kaur, MD
Assistant Professor of Internal Medicine
University of Texas, Southwestern

Brian Rivers, PhD, MPH
Professor and Director
Morehouse School of Medicine, Cancer Health Equity Institute

Attendees

Maureen Achebe, MD, MPH
Physician
Brigham and Women's Hospital/Harvard Medical School

Sherry Adesina, PhD
Senior Medical Science Liaison
Adaptive Biotechnologies

Michael Andreini
President and Chief Executive Officer
Multiple Myeloma Research Foundation

John Becker, PharmD
Associate Director, Hematology Field Medical
Regeneron

Silas Buchanan
Founder and CEO
Institute for eHealth Equity

Zeena Chi
Senior Manager, Patient Advocacy Relations
Genentech

Craig Emmitt Cole, MD
Assistant Professor, Division of Hematology and Oncology
Michigan State University-Karmanos Cancer Institute

Virginie Delwart, MA, MIT, EMT
Patient Advocacy Director
Regeneron

Mark Fiala, MSW, PhD
Assistant Professor
Washington University School of Medicine in St. Louis

Emily Fields
Patient Advocacy
2seventy bio

Monique Giordana, PharmD, BCOP
Senior Director, Medical Affairs
Kite Pharma

Maureen Haas
Executive Director Medical Affairs – Multiple Myeloma
Kite, a Gilead Company

Catherine L. Higgins, PhD
Vice President, Science Programs
Stand Up To Cancer

Rozalynn Hite
Patient Community Director
HealthTree Foundation

Sharita Howe, PharmD
Organized Customer Field Medical
Pfizer

Grant Huang, MD, MPH
Deputy Chief Research and Development Officer – Enterprise Optimization
Department of Veterans Affairs, Office of Research and Development

Patricia Hurley, MSc
Senior Director, Strategic Research Initiatives
American Society of Clinical Oncology

Tom Jiang, PharmD
Associate Scientific Director
Bristol Myers Squibb

Erika Kacer, RN
Nurse Liaison
Karyopharm Therapeutics, Inc

Edward S. Kim, MD, MBA
Physician-In-Chief, City of Hope Orange County
Vice Physician-in-Chief and Professor, City of Hope National Medical Center
City of Hope

Tanya Kogan
Senior Product Manager
Greenphire

Yvens Laborde, MD
Chief Community Medical Officer and Medical Director of Global and Community Health
Ochsner Health

Minnkyong Lee, PhD
Deputy Chief Engagement Officer
National Institute of Health, All of Us Research Program

Trevan Locke, PhD
Assistant Research Director
Duke-Margolis Center for Health Policy

Allison Martin, MS
Director, Regulatory Science and Policy
Sanofi

Lauren Merz, MD, MSc
Hematology Fellow
Mass General Brigham/Dana-Farber Cancer Institute

Erin Miller
Development Manager
Lazarex Cancer Foundation

George Mulligan, PhD
Chief Scientific Officer
Multiple Myeloma Research Foundation

Susana Moscoso, BA, BSN, RN, BMT-CN
Clinical Trial Nurse Navigator
Leukemia & Lymphoma Society

Pralay Mukhopadhyay, PhD
Vice President, Medicine Development Leader
GSK

George Mulligan, PhD
Chief Scientific Officer
Multiple Myeloma Research Foundation

Kimberly Nettles, PharmD
DEI Lead, US Medical Affairs
Johnson & Johnson Innovative Medicines

Stephen Noga, MD, PhD
US Medical Lead, Multiple Myeloma and Immuno Oncology
Takeda Oncology

Ajay Nooka, MD, MPH, FACP
Professor
Emory University

Camille Pope, PharmD, RPh
Chief Medical Lead
Acclinate

Pamela Price, RN
Deputy Director
The Balm in Gilead

Kim Ribeiro, MLS (ASCP)CM, MS
Head, Diversity & Patient Inclusion
AbbVie

Fabian Robles, MSc-HLM, CHI
Clinical Trial Navigator Manager
UT Southwestern Medical Center

Ashley Ruggieri, MS
Director, Alliance Management
Multiple Myeloma Research Foundation

Jamal Saeh, PhD
Executive Director & Global Project Leader
AstraZeneca

Caroline Schenkel, MSc
Associate Director of Analysis and Publications
American Society of Clinical Oncology

Andrew Scott, MBA
Director, Strategic Alliances and Issue Advocacy
Bristol Myers Squibb

Rita Shaknovich, MD, PhD
Vice President, Medical Affairs and Head of Clinical Labs
GRAIL

Rachel Solomon
Lead, US Public Affairs & Patient Advocacy, Oncology
Sanofi

Shelli Spence, MSN
Assistant Scientific Director
AbbVie

Willis Steele, MDiv
Director, Patient Advocacy Hematology
Bristol Meyers Squibb

Mark Stewart, PhD
Vice President, Science Policy
Friends of Cancer Research

Julie Strain, MMH, CMPP
Medical Director, Oncology Strategic Accounts
GSK

Ramita Tandon
Chief Clinical Trials Officer
Walgreen's Health

Christopher Williams
Vice President, Business Development
The Multiple Myeloma Research Foundation

Robert Winn, MD
Director and Lipman Chair in Oncology
VCU Massey Cancer Center

Phylicia L. Woods, JD, MSW
Director, Government Affairs and Alliance Development
GRAIL

Katie Wozniak
Vice President, Clinical Research
Multiple Myeloma Research Foundation

Faiza Zafar
Senior Medical Science Director
Genentech