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901.HEALTH SERVICES AND QUALITY IMPROVEMENT - NON-MALIGNANT CONDITIONS

Engaging Underrepresented Patients in Hematology Clinical Trials through the LLS Impact (Influential Medicine Providing Access to Clinical Trials) Research Grant: A Multi-Institutional Effort

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Introduction: Despite governmental and industry-sponsored efforts, clinical trial participation among rural residents and racial and ethnic minorities remains low. The NIH Revitalization Act of 1993 directed the NIH to establish guidelines for inclusion of women and minorities in clinical research. In 2015, the Food and Drug Administration launched an action plan to improve the quality of demographic subgroup data collection, identify barriers to enrollment, employ strategies to increase participation, and promote transparency of related data. However subsequent studies (Green et al. *Health Aff.* March 2022, Kanapuru et al. *Blood Advances.* March 2022.) showed no improvement in participation of racial minorities, including Blacks and Hispanics since this plan was enacted. Various complex system- and individual-based factors, including lack of clinical trial availability; lack of diversity in the investigator work force; scant patient and provider awareness of clinical trials; lack of trust in the health care system; and issues with access to care-often driven by financial, geographic, or social constraints (Allison et al. Cureus. Apr 2022.), and stringent eligibility criteria are deemed responsible. The Leukemia & Lymphoma Society (LLS) IMPACT (Influential Medicine Providing Access to Clinical Trials) research grant strives to bridge this unrelenting care gap.
Methods: The LLS IMPACT program includes a 5-year research grant which was launched in 2021. The IMPACT grants support the establishment of clinical trial networks involving academic cancer centers ("Hubs") linked to community clinics and oncology centers ("Spokes"). The program's overall goal is to provide patients access to trials through participation at the community sites. Initially, 3 institutional sites were selected to participate. These institutions had unique and tailored strategies to improve engagement of underrepresented patients, including black, indigenous, people of color, Hispanic, Latina/Latino, and people from rural communities in vastly different climates and local cultures. The IMPACT grant expanded to encompass 4 additional sites given the imminent needs and clamor of the hematology clinical trials community (Figure 1A). The catchment areas and strategies employed at each institution are summarized in the table (Figure 1B).

Results: At the start of the grant period, focus was on building clinical research infrastructure and opening non-interventional clinical trials to teach personnel about clinical research and create relationships with patients. Other programs such as webinar series, tumor boards, technological advancements, and educational workshops were also established to enhance engagement among physicians, match patients to clinical trials, and to provide clinical trial education to potential patients. One trial that has seen early success is the CHIVE IMPACT trial, a non-interventional registry and biorepository which has enrolled 24 patients at a rural and underserved site as of July 2023. The purpose of CHIVE is to enroll patients who have clonal hematopoiesis (CH) or are at risk of CH and follow prospectively in efforts to understand risk of progression and potential for early intervention. The Universal Protocol is another biorepository trial which has more than tripled its enrollment number at a community site between 2021 and 2022. Of the 63 patients enrolled in 2022, 66% of them identified as a race other than White.

As our core goal is to increase access to interventional trials, we hope to bring industry sponsored phase II and phase III studies to underrepresented areas that serve a broad patient population. Lack of financial resources, lack of transportation and distance to trial sites, and residual distrust of the medical community (e.g., legacy of Tuskegee experiments) are barriers the grantees are focused on overcoming to enroll the intended populations into clinical trials.

Conclusion: The innovative strategies employed to expand access to clinical trials for underrepresented population at the various institutions through the LLS's IMPACT research grant can be utilized during clinical trials design and implementation phases to improve generalizability of clinical trials in hematologic malignancies. In the third year of this program, 7 participating sites are engaging impactful strategies (Figure 1B) which will be reported at the end of the grant period.

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Figure 1A: Geographic location of IMPACT programs

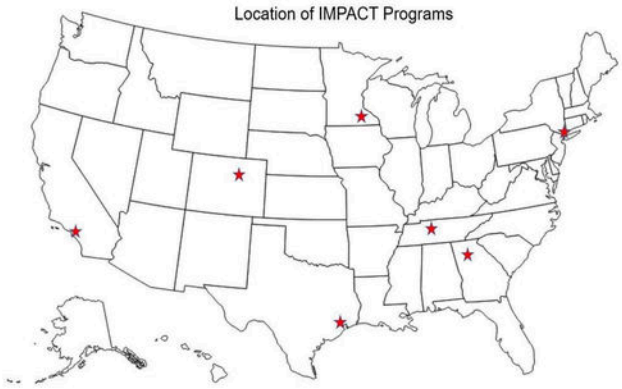

Figure 1B: Institutions, catchment areas, and strategies included in IMPACT research grant

Institution	Catchment Area	Strategies
MD Anderson Cancer Center	South Texas (≥50% of lymphoma and myeloma patients in this area will be Hispanic or qualify as rural)	Establish Clinical Trial Network of South Texas (CTN-ST) to enable high-quality clinical trial deployment at UT San Antonio Mays Cancer Center and community Oncology Centers in South Texas (particularly the Laredo Medical Center and the Rio Bravo Cancer & Blood P.A.)
University of Colorado	Major population centers (metro Denver, Fort Collins, Colorado Springs), rural Colorado and the Rocky Mountain Region	Engage patients in the community through nurse navigators who will work in community oncology centers to facilitate clinical trials and outreach efforts Create/expand virtual remote clinical trials operations at the University of Colorado designed to specifically assist these patients to overcome practical barriers to clinical trials enrollment and participation. Work with the Colorado University Anschutz Center for Native American Health Care to specifically address unique social and practical barriers to clinical trials participation by Native Americans in the Rocky Mountain Region
City of Hope (COH)	Catchment area of 9,365 square miles, including Los Angeles, Orange, Ventura, Riverside, and San Bernardino counties serving a multi-racial, multi-ethnic community of 17 million people.	Optimize clinical network and increase research capacity at Community and Affiliate Network (CAN) sites in Southern California. CAN sites will serve geographically proximal practice sites, which will refer patients for treatment on clinical trials at either the CAN site itself or at the main Duarte campus. Initiate a new CAN site yearly over a 5-year period to allow a wider area of Southern California residents to have access to high quality and impactful clinical trials in Hematology.
Winship Cancer Institute of Emory University	State of Georgia (~10 million people) with both urban and rural sites with high rate of poverty, and limited access to tertiary care centers	Establish the Georgia Blood Cancer Trials Network (BCTN) which will bring together sites from around the state, many of which are already engaged in trials through the NCORP funded Georgia Center for Oncology Research and Education (CORE)
Mayo Clinic Rochester (MCR)	About 70% of patients referred to MCR come from 5 states: MN, WI, IA, SD and ND, states inhabited by 10,483,946 people living primarily in a rural setting. Leverages Minnesota Cancer Clinical Trials Network, a network of 35 clinical sites throughout rural, underserved communities in Minnesota, Wisconsin, and Iowa, as well as metropolitan Minneapolis.	Full activation model: Open clinical trials at local sites, which includes consenting and patient screening. Hybrid Collaborative Model: Consenting, screening +/- initiation of parts of therapy are done at Mayo clinic, while most of active therapy and safety assessment are done at local sites.
Vanderbilt University Medical Center (VUMC)	The Vanderbilt Health Affiliated Network (VHAN) encompasses 12 health systems and 61 hospitals, including a formal affiliation with Baptist Memorial Healthcare Corporation (BMHCC), which covers 111 counties totaling 4.3 million people, including the most indigent population in the US.	Open Clinical Trials in Memphis and surrounding areas Improve physician provider engagement through webinar series, tumor board, clinical trial newsletters and annual symposiums. Utilize technology solutions, like Redcap, to enhance clinical trial enrollment. Launch patient focused community engagement programs, including ResearchMatch, VUMC Recruitment Innovation Center (RIC) Program, community education town halls, and an IMPACT Community Advisory Board
Weill Cornell Medicine	Borough of Queens (2.3 million residents) and borough of Brooklyn (2.5 million residents)	Clinical Trial Navigation: Oncology navigators will provide one on one assistance to blood cancer patients. Create fund to offset trial related expenses for patients. Conduct clinical trials at community centers. Share the financial burden for staffing providers with the community cancer centers. Implement community-based workshops to inform community residents about blood cancers and clinical trials. Workshops for primary care physicians and community-based oncologists

Abbreviations: IA: Iowa; MN: Minnesota; ND: North Dakota; SD: South Dakota; WI: Wisconsin

Figure 1

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