Barriers and Strategies for Increasing Diversity in Clinical Research

Lisa Diamond, MD, MPH

October 10, 205

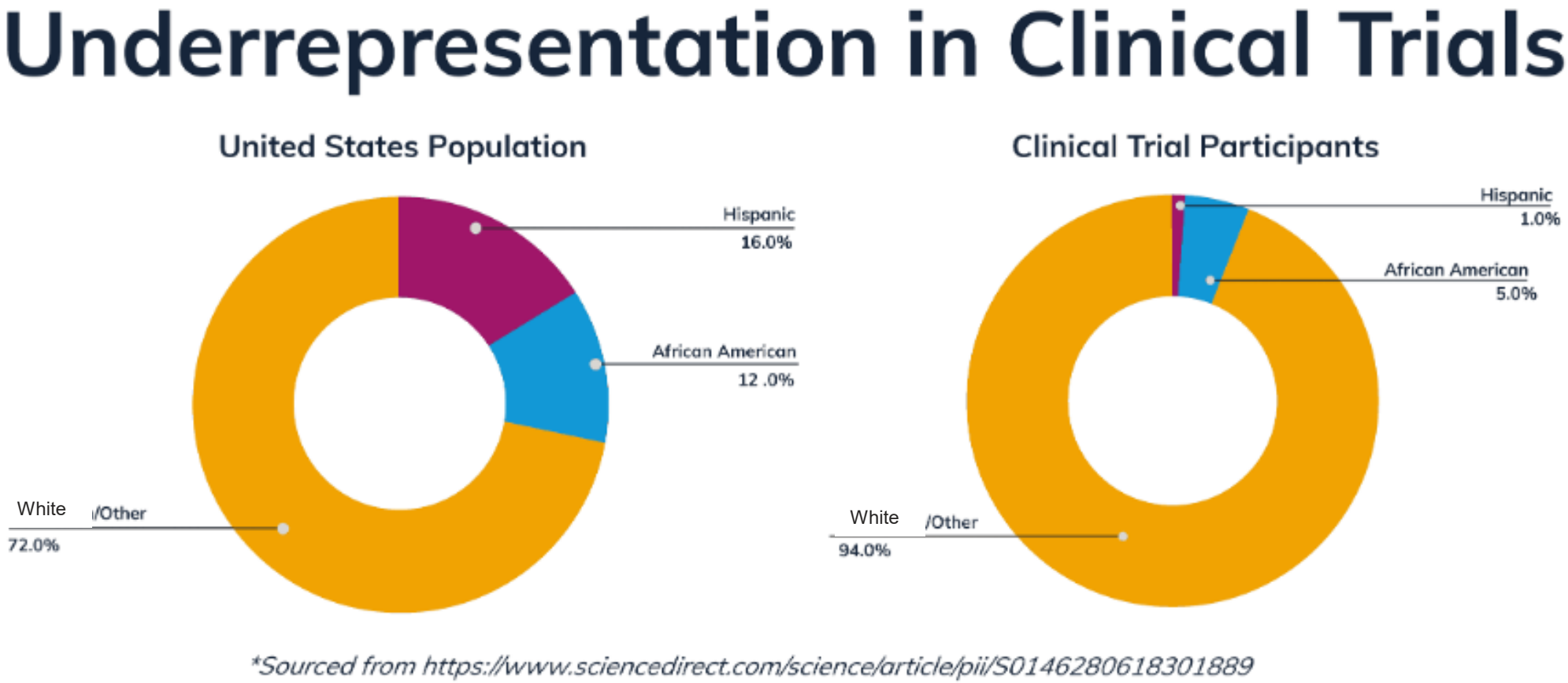
Memorial Sloan Kettering Cancer Center

Presentation Outline:

1. Diversity of clinical trials in the US
2. Barriers to clinical trial enrollment based on race/ethnicity and language and some solutions from the literature
3. What's happening at MSK

Diversity of Clinical Trials in the US

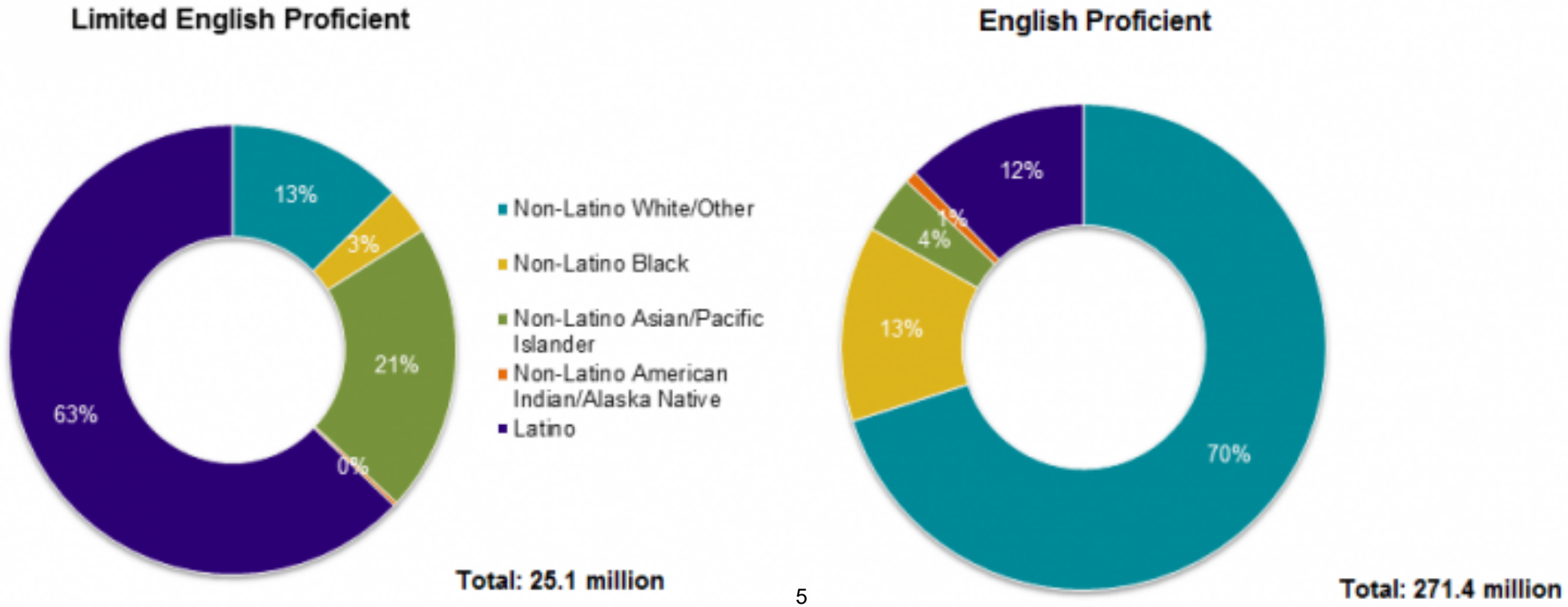
Composition of Racial/Ethnic Groups in Clinical Trials



*Sourced from https://www.sciencedirect.com/science/article/pii/S0146280618301889

Focus on Hispanic/Latinx Population and Language

- Hispanic/Latinx largest racial/ethnic group after non-Hispanic whites.
- Individuals with NELP in US more likely to be Hispanic/Latinx or Asian than English-speakers
- 62% of population with LEP is Hispanic/Latinx, compared to 13% of English-proficient population
- Including Hispanic/Latinx people with NELP in research important pathway to improve diversity in clinical trials
- Hispanic/Latinx populations are extremely heterogenous – recruitment with diversity in country of origin important



Importance of Diversity in Clinical Trials

Equity and Justice

- Trial enrollment should accurately reflect the burden of the disease
- Access to high quality care
- Access to treatments before readily available

Generalizability

- There may be differences in effectiveness of treatment or in side effects
- Inability to perform subgroup analyses
- Genetic factors (a.k.a. pharmacogenomic differences) may impact drug metabolism, affecting both toxicity and efficacy

Patients with a non-English language preference (NELP) are less likely to be recruited and enrolled in research studies

Barriers to Clinical Trial Enrollment by Race/Ethnicity and Language and Some Solutions from the Literature

There are multilevel barriers to enrolling patients with NELP and other underrepresented groups into research studies

Clinician Level

- Lack of knowledge on what is needed to recruit this population
- Uncertainty about informed consent processes for patients with NELP
- Biases about a patient with NELP ability to comply with the rigors of a research study
- Lack of offer of CT = no participation

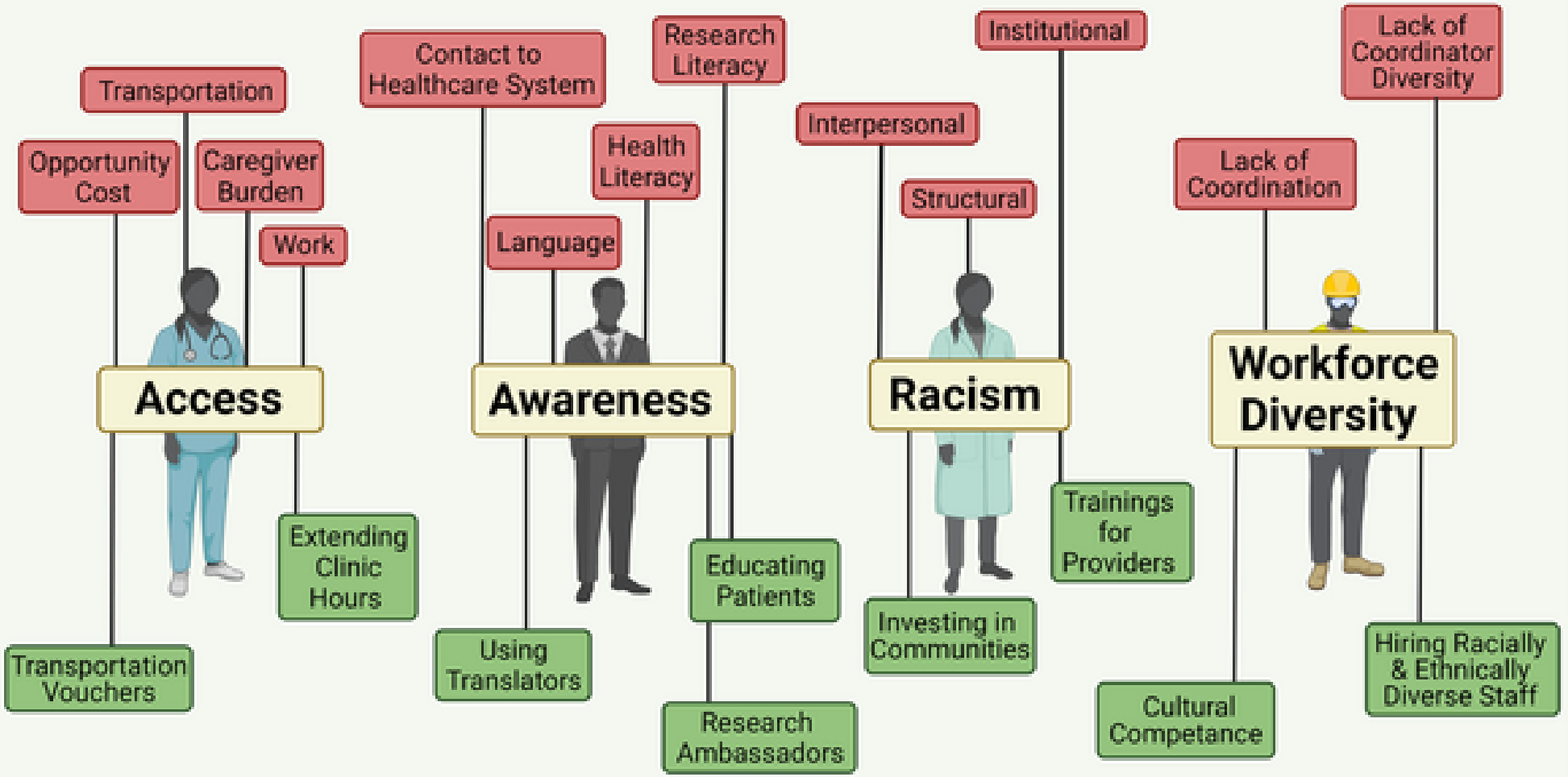
Healthcare System Level

- Translation of informed consent and other research documents
- Provision of interpreters and/or bilingual and/or bicultural research staff services
- Systemic bias

Patient Level

- Difficulties navigating the health care system
- Mistrust in the system and/or clinicians based on historical mistreatment
- Lack of knowledge about cancer and its treatment
- Social determinants of health needs (e.g., transportation, childcare, work)
- Intersectionality of NELP with literacy, immigration status

Barriers to Clinical Trial Participation



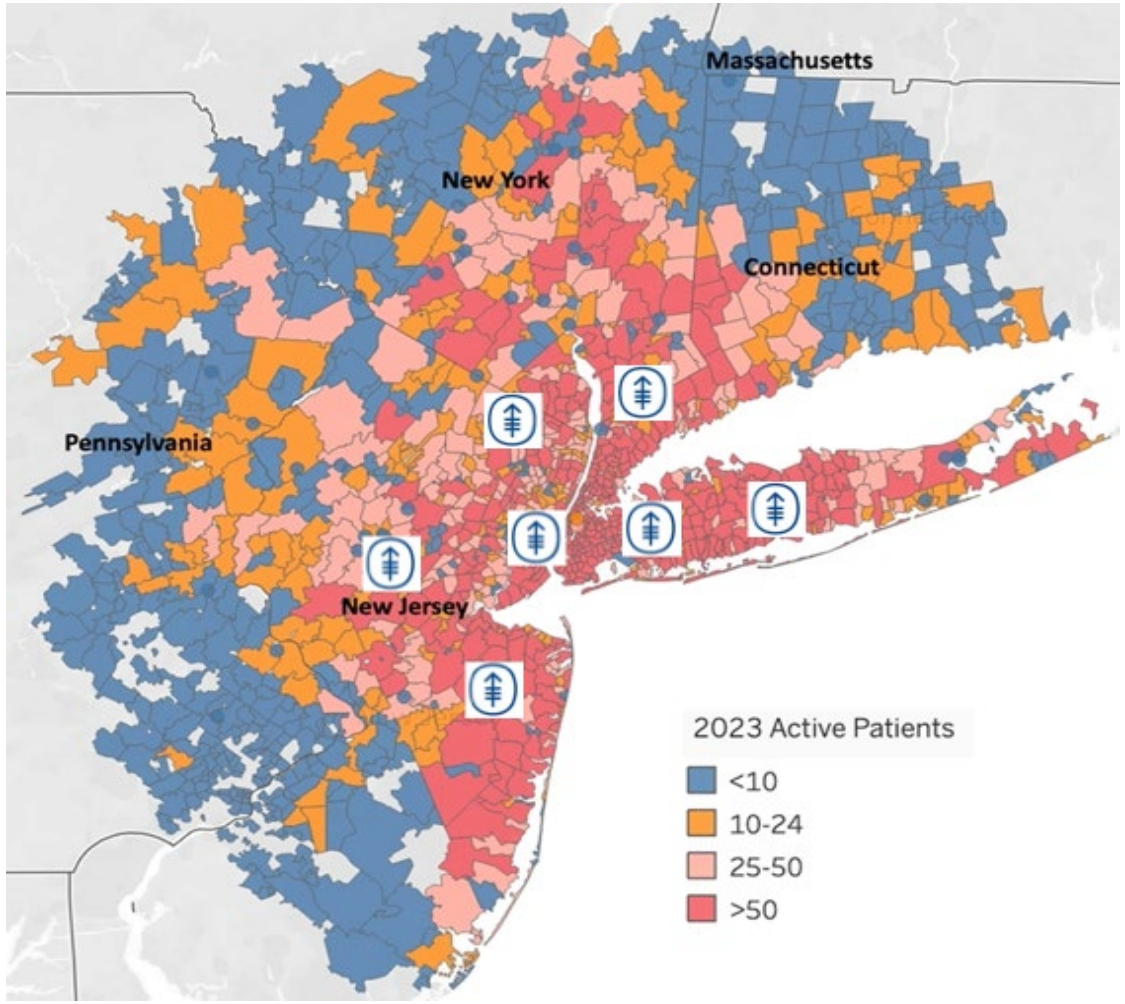
Solutions to Clinical Trial Participation

What is Happening at MSK: Demographics

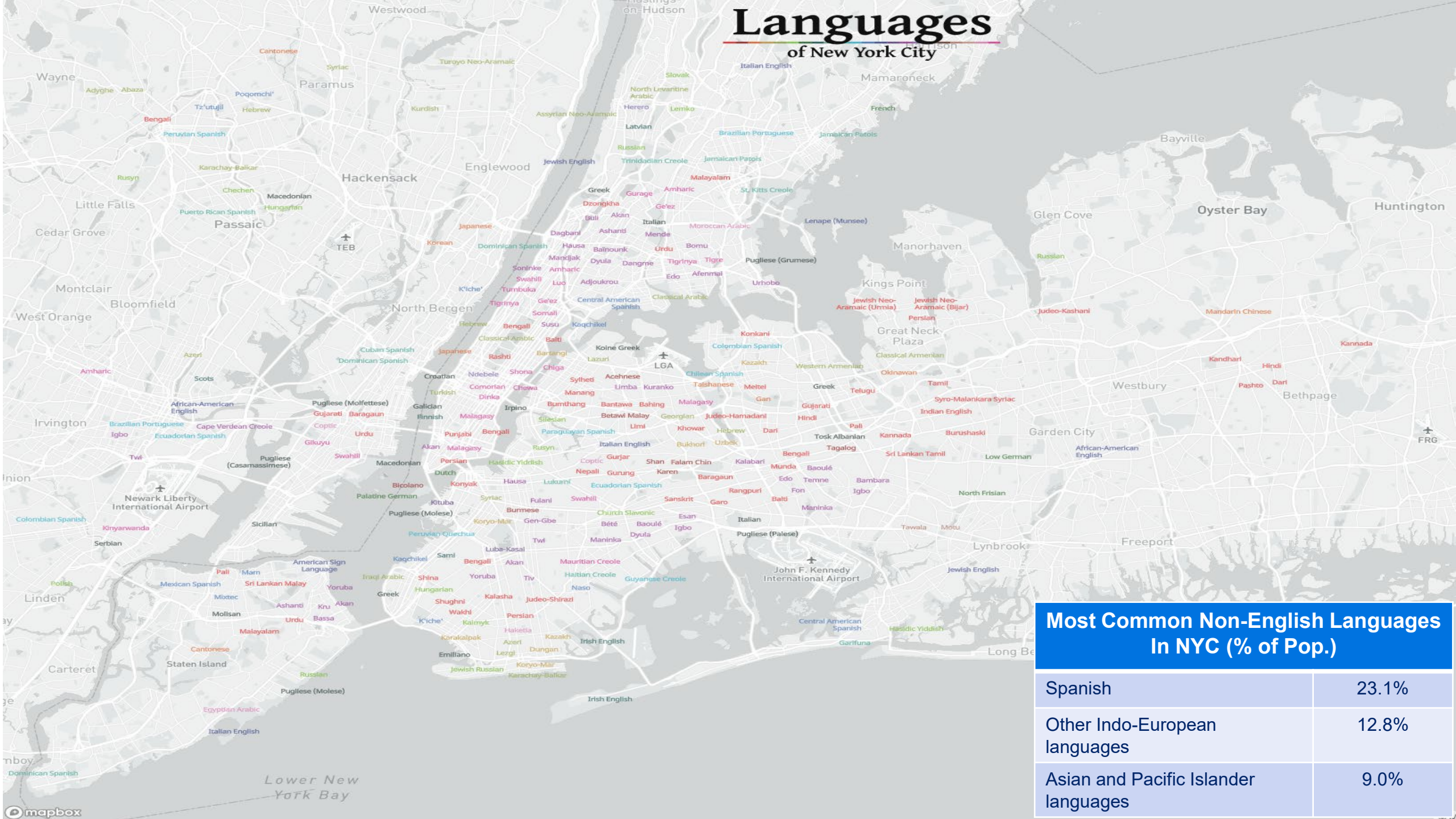
MSK Catchment Area

COMMUNITY OUTREACH AND ENGAGEMENT

- 150-mile radius around the Manhattan campus
  - 90% of patients, 88% clinical trials pts
- 7 clinical sites
  - Manhattan, NJ, Westchester, Long Island
- Unique cancer risks, and differences in outcomes
- 32% of patients live in NYC
  - Stark cancer differences between neighboring communities

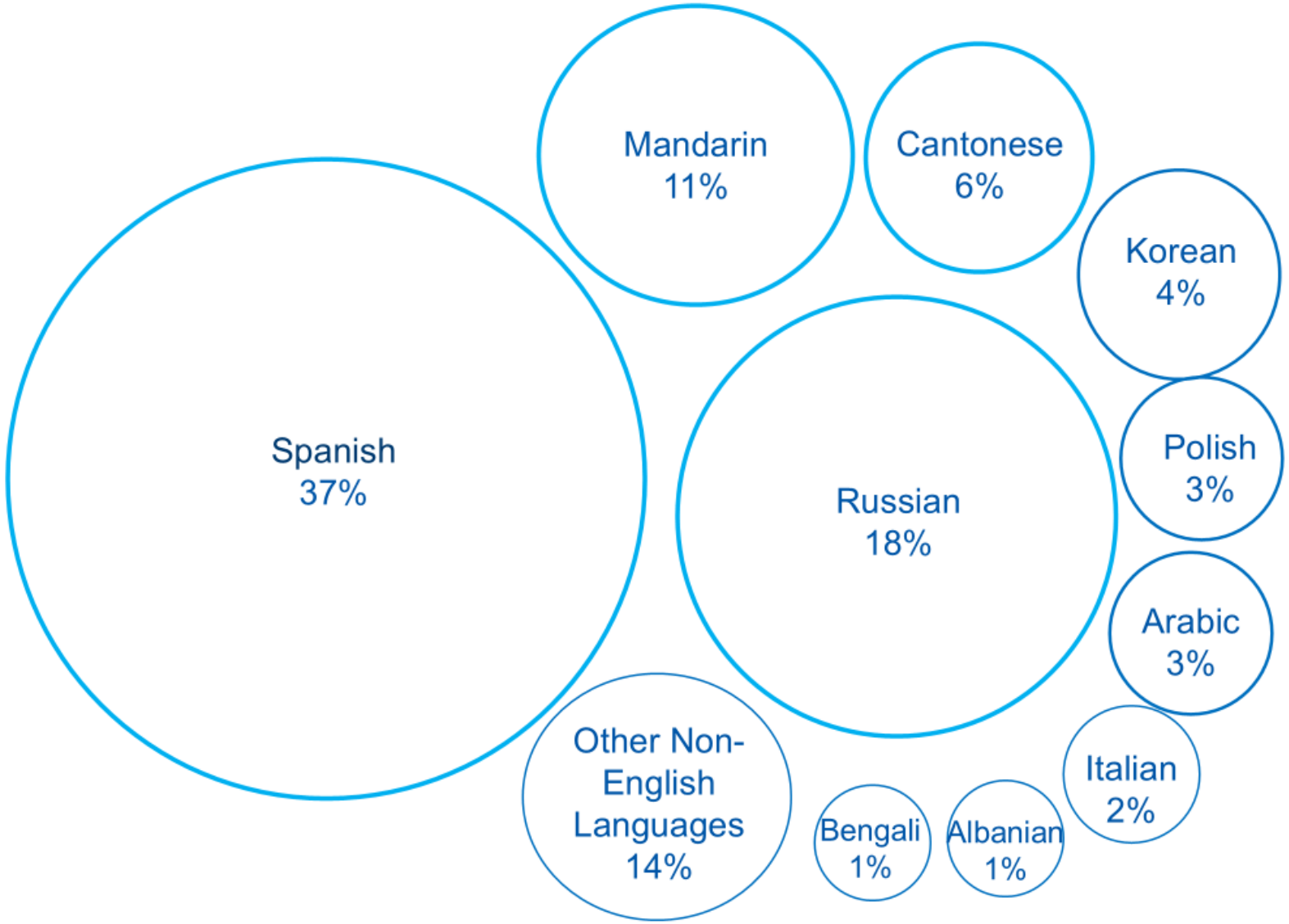


Languages
of New York City



Most Common Non-English Languages In NYC (% of Pop.)	
Spanish	23.1%
Other Indo-European languages	12.8%
Asian and Pacific Islander languages	9.0%

Top 10 Languages at MSK



MSK Statistics on CT Enrollment

Only 9.6% of CT enrollees reported Hispanic/Latinx ethnicity

4% reported NELP (Spanish 1%)

Resources at MSK:

- Cancer Health Equity Research Program(CHERP)
- MSK Cancer Alliance
- Patient Reported Outcomes – Community Engagement and Language (PRO-CEL) Core

What is Happening at MSK: Evidence from the Literature

The Oncologist, 2023, **28**, 131–138
https://doi.org/10.1093/oncolo/oyac218
Advance access publication 2 November 2022
Original Article

Associations Between Race/Ethnicity, Language, and Enrollment on Cancer Research Studies

Ogochukwu M. Ezeoke[1,2,3], Gary Brooks[2], Michael A. Postow[3,4], Shrujal Baxi[3], Soo Young Kim[3], Bharat Narang[3], Lisa C. Diamond[*,3,4,5]

[1]Department of Pediatrics, Ann and Robert H. Lurie Children's Hospital, Chicago, IL, USA
[2]College of Medicine, State University of New York Upstate Medical University, Syracuse, NY, USA
[3]Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY, USA
[4]Weill Cornell Medical College, New York, NY, USA
[5]Department of Psychiatry and Behavioral Sciences, Memorial Sloan Kettering Cancer Center, New York, NY, USA

[*]Corresponding author: Lisa C. Diamond, MD, MPH, Assistant Attending Physician, Department of Medicine, Memorial Sloan Kettering Cancer Center, 485 Lexington Avenue, 2nd Fl, New York, NY 10017, USA. Tel: +1 646 888 4246; Email: diamondl@mskcc.org

Study Objectives and Methods

Objective:

To determine whether differences in patients' race/ethnicity, preferred language, and other factors were associated with enrollment in oncology research studies

Methods:

Retrospective cross-sectional analysis of all adults (>18 and ≤90) seen at MSK between 2005 - 2015, examining if enrollment to a research study varied by race/ethnicity, preferred language, comorbidities, gender, and age

Results

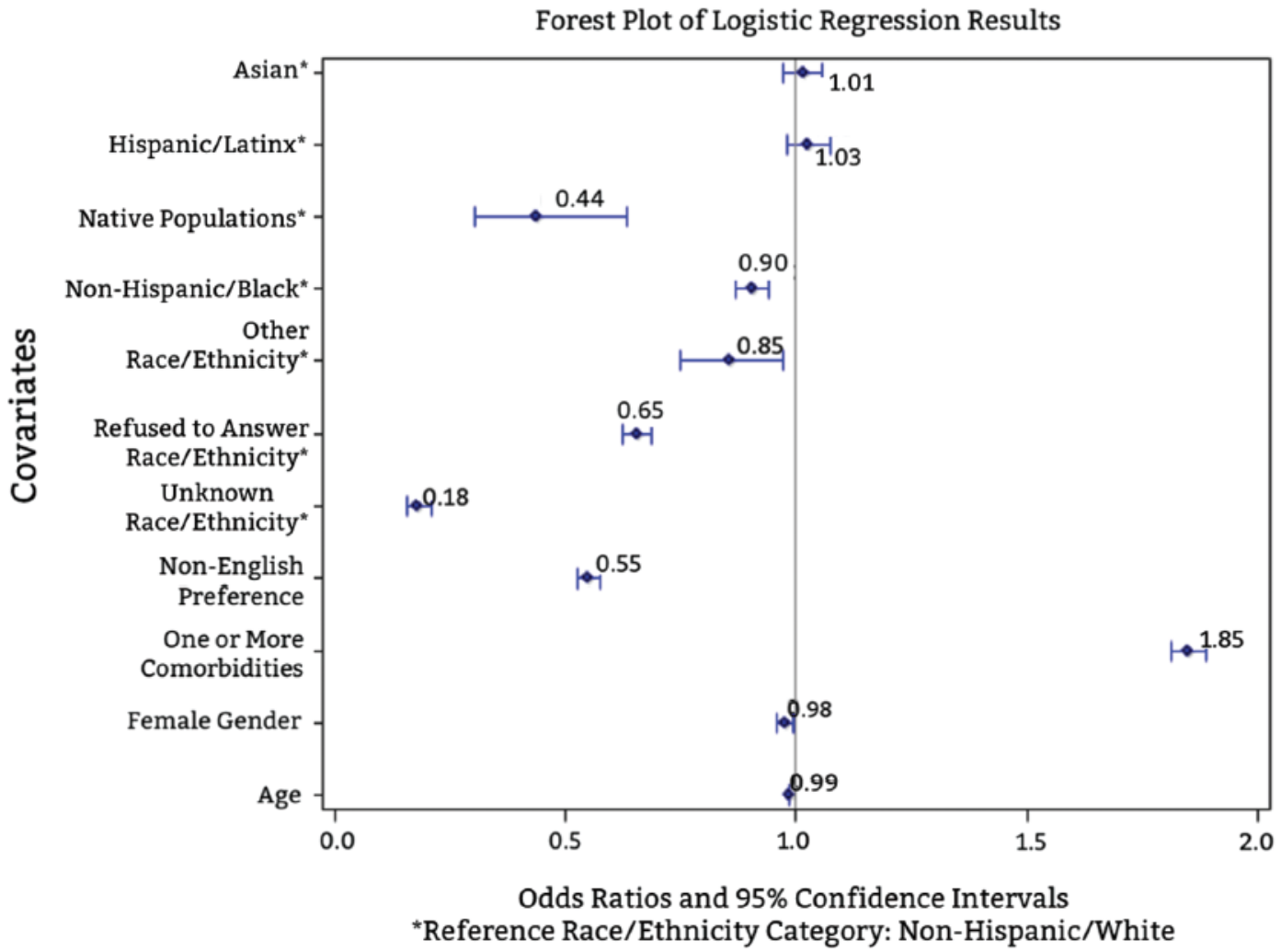


Figure 1. Logistic regression for research study enrollment.

Conclusions

- We identified differences in research study enrollment based on:
  - Preferred language
  - Racial/ethnic categories: Native-Populations, Other, Unknown, or Refused to Answer
  - Lower odds of enrollment among Non-Hispanic/Black patients with comorbidites and English language preference (otherwise positive predictors of enrollment)
  - Further investigation needed to design targeted interventions to reduce disparities in oncology research study enrollment, with particular focus on language diversity
  - Language barriers need to be addressed while planning studies, not as an afterthought.

What is Happening at MSK: Resources

Cancer Health Equity Research Program – CHERP

Work with MSK investigators in diseases with known disparities

Work with OneMSK sites that see more diverse patients

Open MSK trials at external CHERP sites

Refer patients from external CHERP sites to MSK for trials

Work with the community oncologists to find trials at MSK and facilitate referrals to MSK for trials or other care not available at the community site (e.g. BMT)

CHERP Sites

NYC Health + Hospitals

Largest public health care system in the United States. They provide essential services to more than one million New Yorkers every year.

NYC Health + Hospitals/ Kings

Demographics: 84% Black, 6% Hispanic, 1% Asian, 6% other, 3% white.

Disease Focus: Breast, Prostate, Hematology

NYC Health + Hospitals/ Queens

Demographics: 46% Black, 27% Asian/South Asian, 18% Hispanic

Disease Focus: Breast, Colorectal, Gastrointestinal, Prostate, & Lung

NYC Health + Hospitals/ Lincoln

Demographics: 59% Hispanic, 29% Black, 9% other, 1% Asian, 2% white

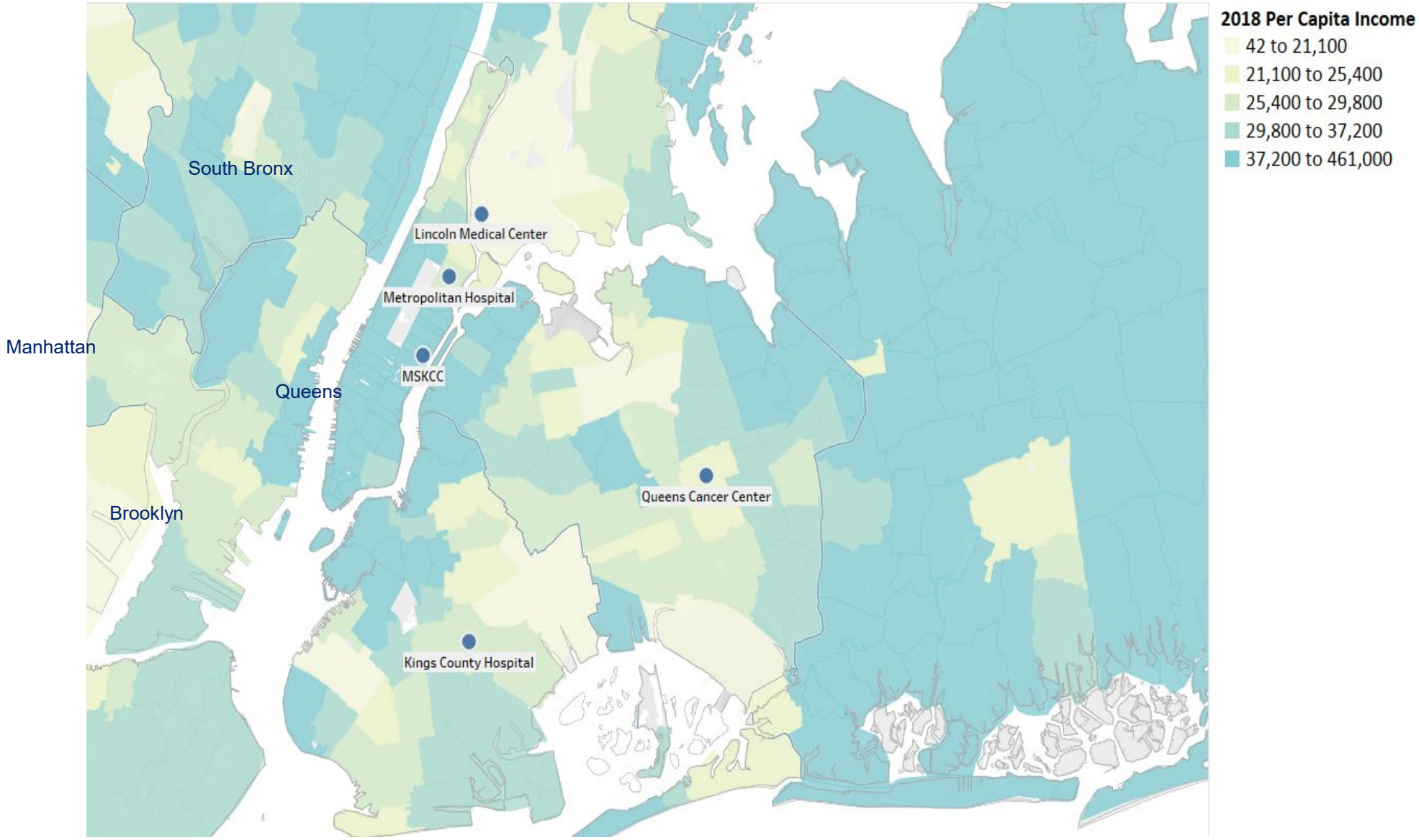
Disease Focus: Breast and Lung

NYC Health + Hospitals/ Metropolitan

Demographics: 57% Hispanic, 22% Black, 13% other, 2% Asian, 5% white

Disease Focus: Breast, Colorectal, Prostate, & Lung

CHERP Site Locations



Program Overview: Study Oversight

CHERP Site PI Oversight

Each CHERP site has a dedicated MSK Research Project Associate on site to manage and oversee site activation, amendments, patient assessments, specimen collections, data entry, quality assurance and compliance, and patient referrals.

Regulatory Oversight

MSK is the Institutional Review Board (IRB) and Privacy Board of Record for the CHERP Sites

MSK maintains Human Subjects Protection and HIPAA training for all site investigators on the face page

MSK maintains Good Clinical Practice for all site investigators on the face page as instructed by the Sponsor

Regulatory documents related to MSK as the IRB of Record are filed in MSK's Protocol Information Management System (PIMS)

Integrated Mutation Profiling of Actionable Cancer Targets to Eliminate Disparities

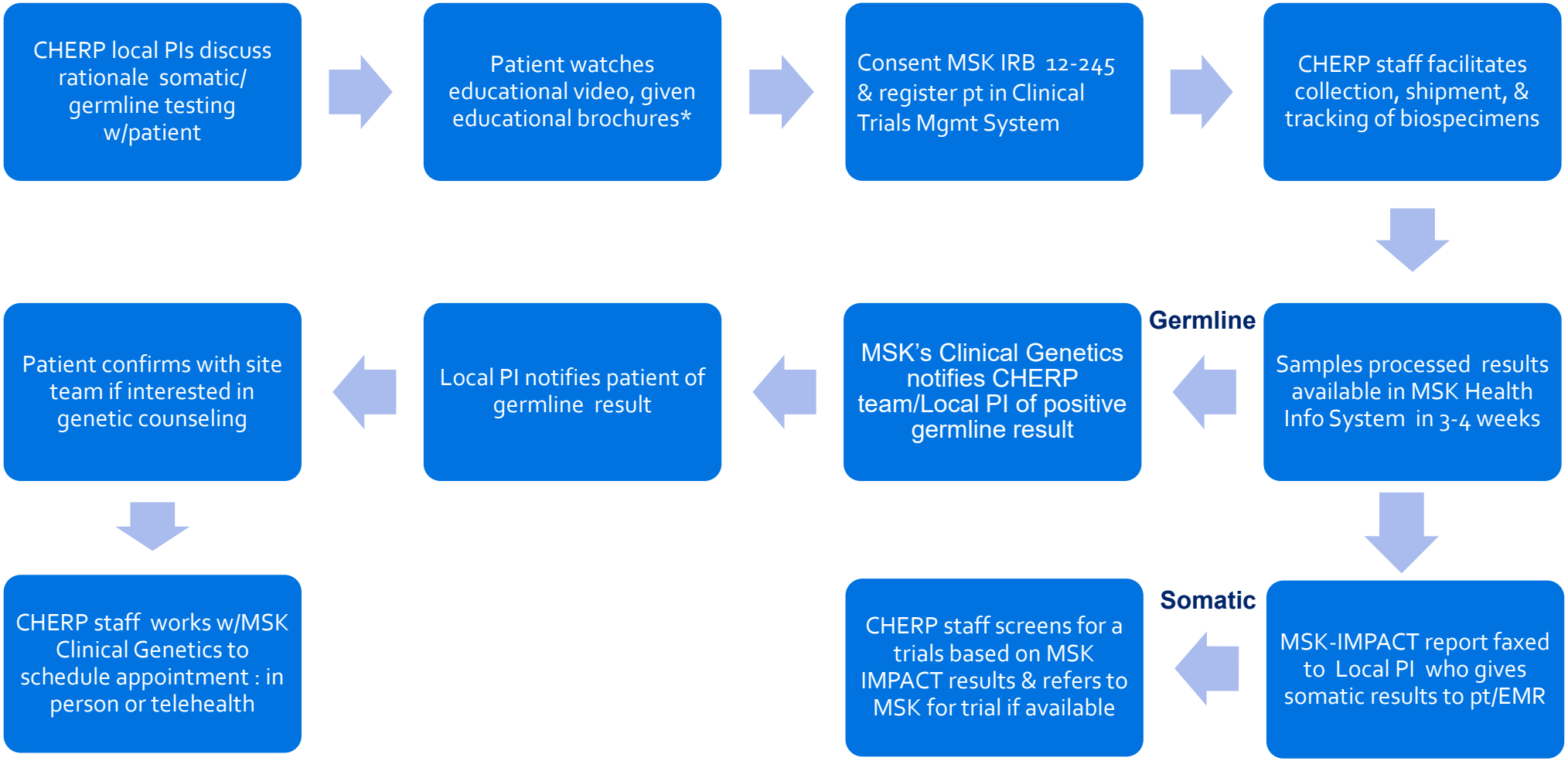
Inspired by White House Cancer Moonshot

Identification of actionable mutations can lead to clinical trials of novel targeted therapies = Precision Medicine

Enrollment of patients underrepresented in clinical trials will allow detection of differentially expressed molecular drivers of cancer disparities.

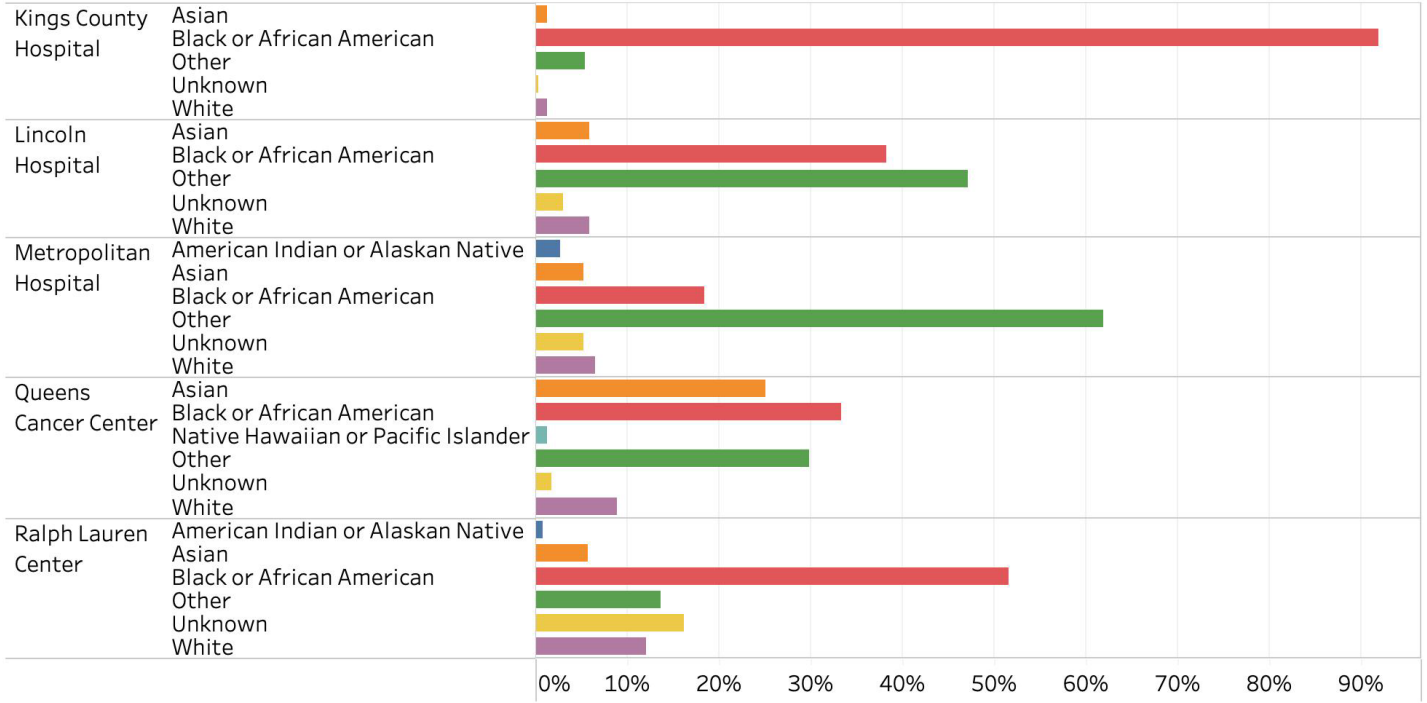
Accrual began 8/2016 at Queens Cancer Center(QCC)

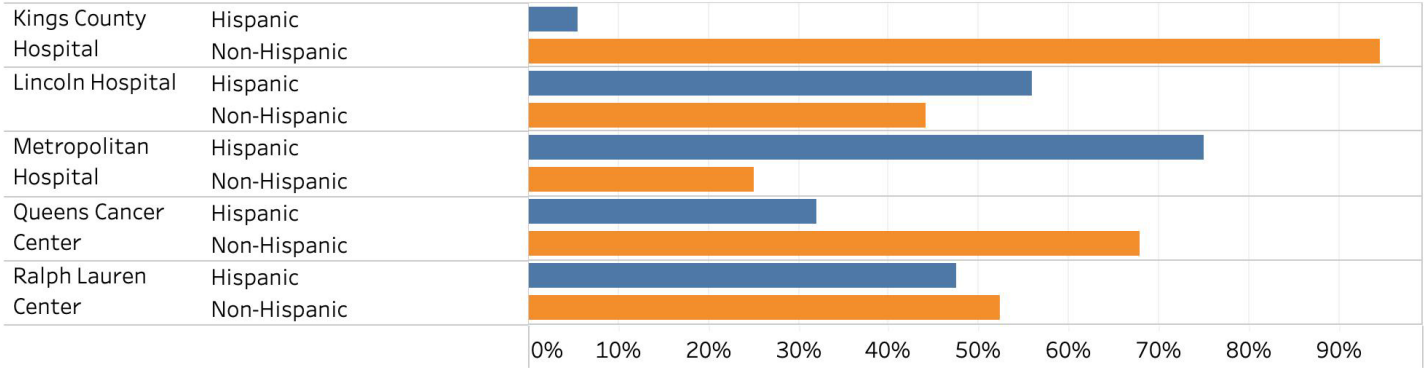
Workflow Genomic Profiling at CHERP Sites



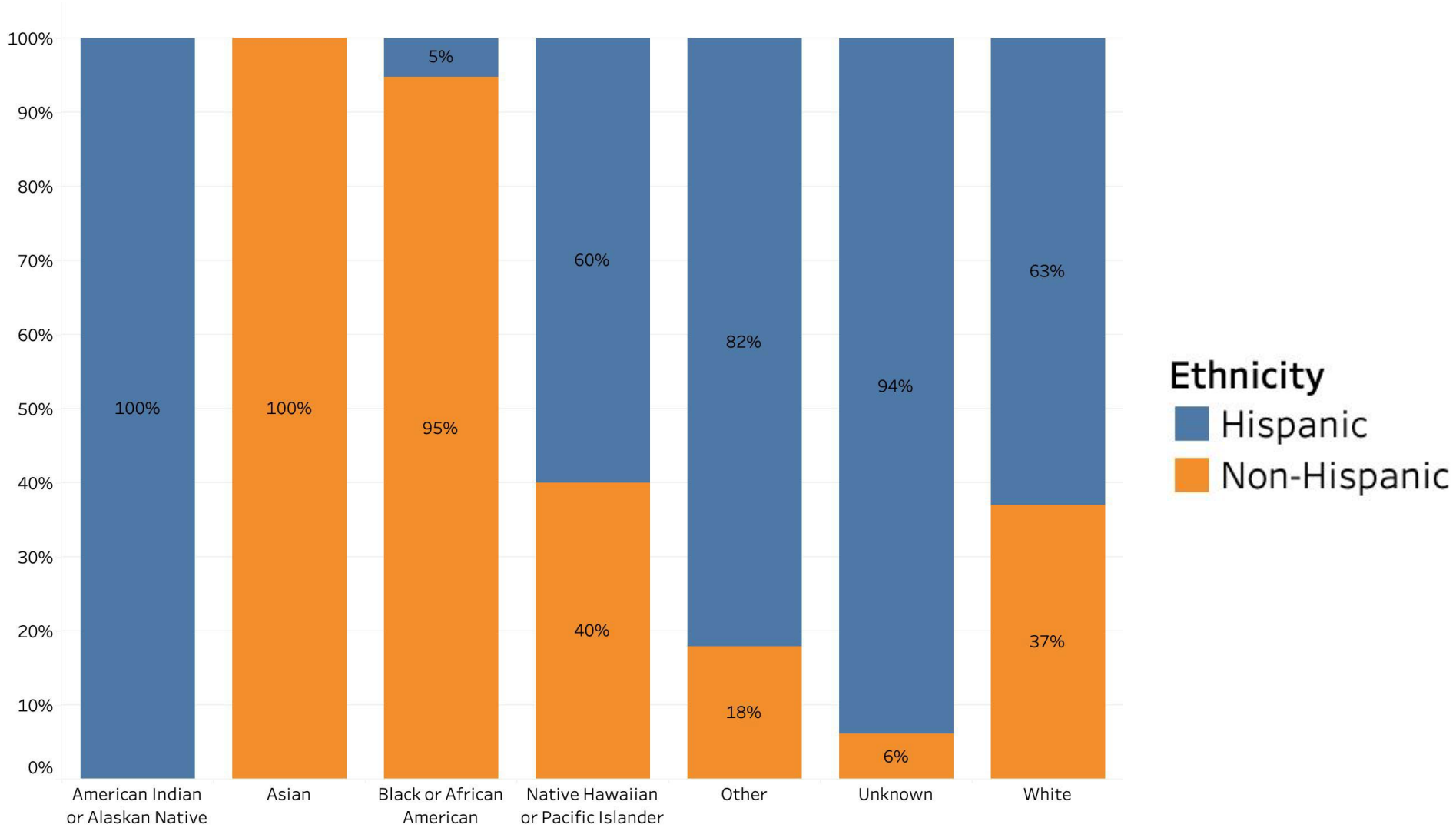
**All services and materials are available in the patients' preferred language*

Race and Ethnicity of IMPACT-ED Participants (n=968) by Location



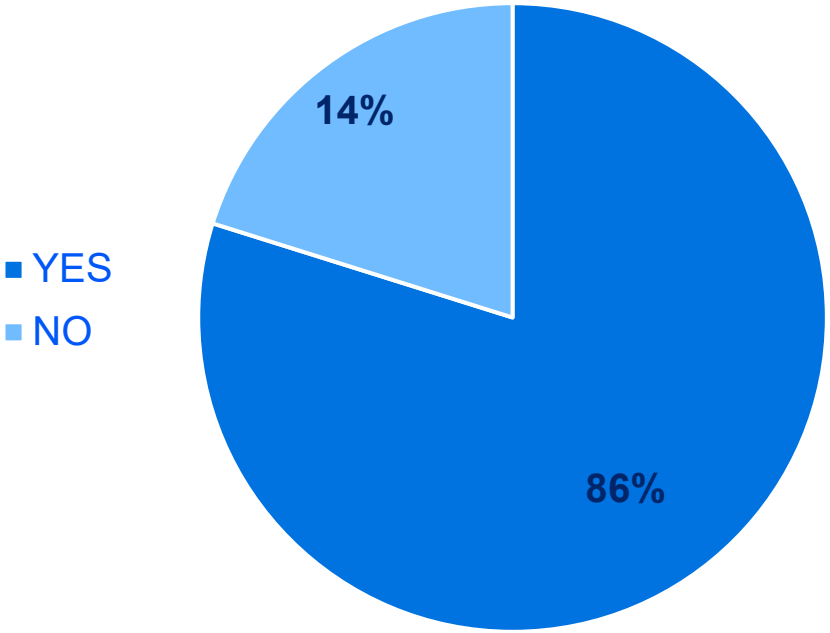


Ethnicity by Racial Group – IMPACT-ED Participants

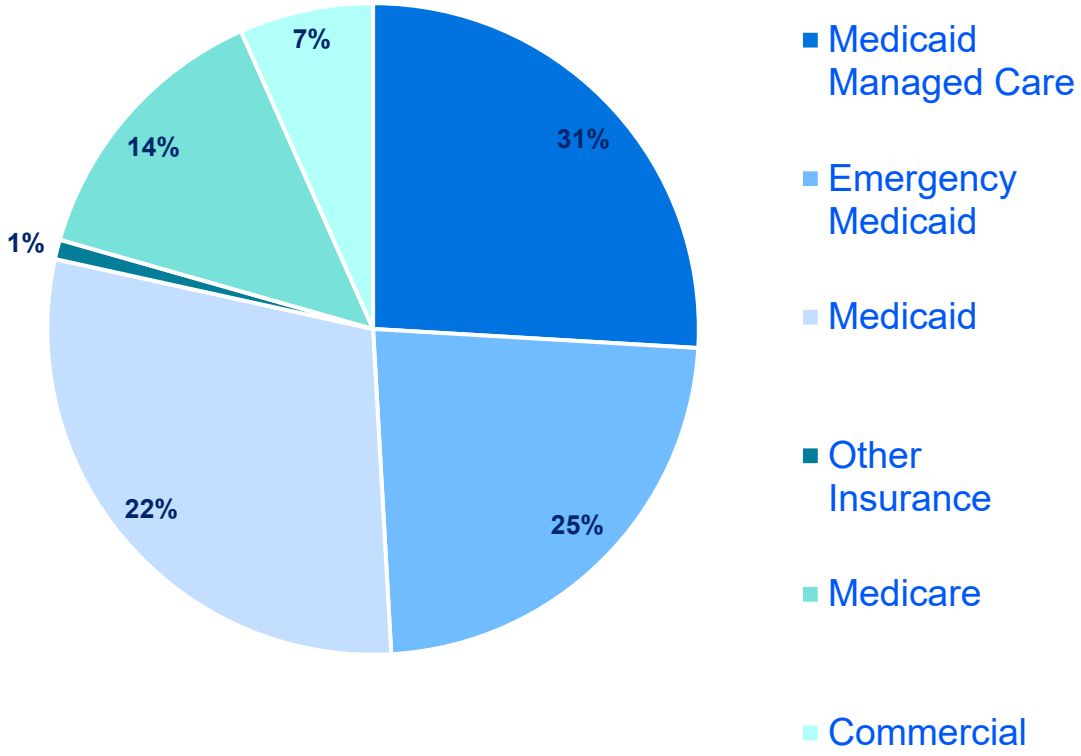


Insurance Coverage IMPACT-ED Participants

Insurance Coverage



Insurance Type



The Office of Health Equity: Research Program Team

Carol Brown, MD, Sr. VP and Chief Health Equity Officer

Tom Reynolds, Senior Director
reynoldt@mskcc.org

Lisa Jean & Kinman Bailey, Research Project Associates

Safety Net Hospital Partnerships

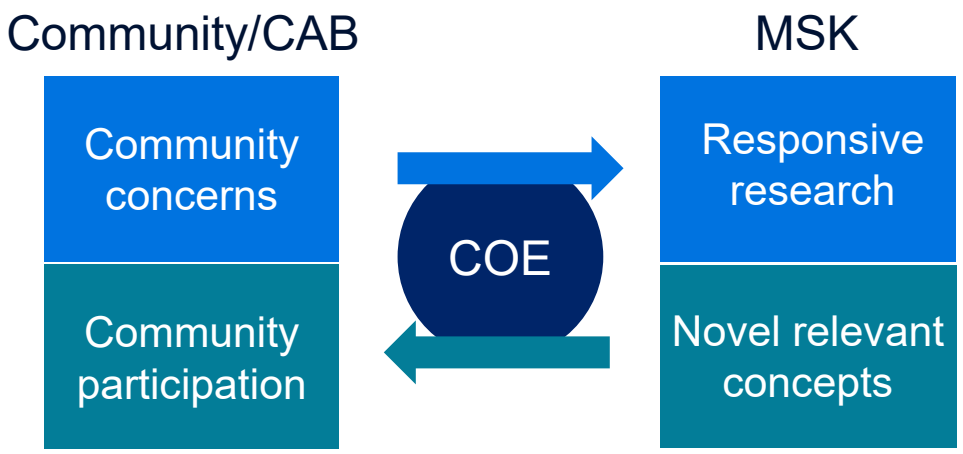
Jamaica Hospital Medical Center

- JHMC serves over 2.4 million – many at-risk
  - High rates of colorectal, breast, prostate, and late-stage lung cancer
- MHU outreach and community health worker engagement
- MSK/Jamaica annual Cancer in At-risk Populations Conference series
- Lung screening outreach

Impact (2025): $188 million state grant for new cancer center, in collaboration with MSK

Supporting Community Engagement in Research at MSK

Bidirectional germination of new community-based research and projects



COE Facilitation

- Defining areas of alignment
- Establishing project-specific CABs
- Engaging CRTEC for trainee participation
- Communicating implications and future directions

Examples of COE-facilitated Research and Integration across Programs

Mechanisms of Disease

- Racial differences of gamma secretase/ NOTCH signaling in TNBC (Gilchrist, Li, U54 CA137798) [ET]
- Social Indicators and Tumor Biomolecular Profiles in Breast Cancer(Goel, R37CA288502) [PSR]

Cancer Prevention and Risk Mitigation

- HTLV1 associated lymphoma precision prevention (Horwitz, Leukemia and Lymphoma Society, P92927) [CR]
- D&I Research in HPV Control (Budhu, U54CA137788, ESI) [PSR]

Drug Development

- Structural, chemical, and cellular probing of a new anticancer target: HIF-coactivator complexes (Tan, Gardner, U54CA137788) [SCB, CR]

Lung Cancer

- Genetic Ancestry, Germline Mutations, and Lung Adenocarcinoma (Carrot-Zhang, R00CA259223) [PSR]

Health System Partnerships

- NYC Metro Regional Cancer Collaborative
  - COE Partnerships
  - Share catchment area community survey results, educational materials, programming, policy initiatives

Impact: NYS legislation: All NYS Medicaid recipients can receive comprehensive cancer center care

MSK is the leading provider of Medicaid cancer care in the state

- NYS Cancer Consortium for NYS Comprehensive Cancer Control Plan
  - Dr. Jennifer Leng on steering committee

Impact: Patient navigation legislation in concert with ACS

  - Healthy Eating Active Living Action Team

Impact: Food insecurity screening at safety net hospitals

MSK Community Partners

MSK Care Partners & MSK Cancer Alliance

October 1, 2025

Memorial Sloan Kettering Cancer Center

Shift from MSK Cancer Alliance to MSK Care Partners

- The Care Partners model is an evolution of the Alliance, offering more tailored knowledge-sharing, focused education, and collaborative opportunities.
- Potential Care Partners undergo a robust Concordance Assessment, encompassing Standards of Care™, Resources and Capabilities, clinical outcomes, and site visits.
- Upon a satisfactory conclusion and finding of concordance, MSK Care Partners receive access to branded marketing, facility co-branding, MSK guidelines and protocols, and educational and research support.

MSK Care Partner

Hartford HealthCare

- Hartford HealthCare at St. Vincent's Medical Center and the Blackrock outpatient center is the first MSK Care Partner
- Across the HHC System
  - 8.2% of the population report Hispanic/Latinx ethnicity
  - 6% report NELP
  - 1% clinical trial accrual for Hispanic/Latinx
  - Countries of origin:
    - Peru
    - Dominican Republic
    - Puerto Rico
    - Mexico

Concluded Relationship

Lehigh Valley Cancer Institute

- From 2016 until July 2025, Lehigh Valley Cancer Institute was part of the MSK Cancer Alliance, a partnership that ended following Lehigh's merger with Jefferson Health.
- Ongoing clinical trials and research initiatives at the time of the separation will proceed to completion, and all patients currently enrolled will be able to finish their participation as originally intended.

Lehigh Valley Topper Cancer Institute

Future MSK Care Partner

Program Growth

- MSK is actively working to bring on a second MSK Care Partner – **Miami Cancer Institute**, which is currently undergoing a Concordance Assessment to review system-wide and location specific practice, process, and quality
- **MCI** has been an MSK Cancer Alliance member since 2017 and is engaged in numerous research studies with MSK
  - 77% of the MCI patient population report Hispanic/Latinx ethnicity
  - 35% report NELP
  - 1% clinical trial accrual for Hispanic/Latinx
  - Countries of origin:
    - Cuba
    - Puerto Rico
    - South America
    - Mexico

- MSK plans to continue to grow the MSK Care Partners program with additional members over the next several years

Other Relationships

Health Equity

Jamaica Hospital Medical Center (MediSys)

- MSK and Jamaica Hospital formalized a 5-year partnership in January 2023, renewed in June 2024, aimed at expanding cancer care access and improving health equity.
- MSK's goals for the relationship is to enhance access for underserved populations, diversify clinical trial participation, and extend specialty care. Jamaica's goals are to build a comprehensive cancer program, recruit oncology staff, and integrate MSK's expertise into their practice.
- Across the system:
  - 41% of the population report Hispanic/Latinx ethnicity
  - 29.5% report NELP
  - XX% clinical trial accrual for Hispanic/Latinx
  - Countries of origin:
    - Dominican Republic
    - Guyana
    - Jamaica
    - Bangledesh
    - Ecuador
    - Trinidad and Tobago
    - Haiti

Patient Reported Outcomes – Community Engagement and Language Core Facility

Thomas M. Atkinson, PhD
Lisa C. Diamond, MD, MPH
Andrew Vickers, PhD

PRO-CEL Core Facility

Core Center Support Grant (NCI 2 P30 CA008748-55) Shared Resource to support investigators who wish to implement patient- or other self reported outcomes into clinical research or routine care while encouraging engagement of socioeconomic, linguistic, and culturally diverse populations and community members from the MSK catchment area.

PRO-CEL Core Facility Services

Patient-Reported Outcomes (Research)	Patient-Reported Outcomes (Clinical Care)	Qualitative Research Expertise	Language Expertise	Community Engagement
Thomas Atkinson, PhD	Andrew Vickers, PhD	Jaime Gilliland, MA	Lisa Diamond, MPH, MD & Javier Gonzalez, MFA	Francesca Gany, MD, MS & Lisa Diamond, MPH, MD

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BI-MONTHLY TECPRO VIRTUAL TRAINING

VIA ZOOM PLATFORM

WORKSHOP

MSK research support staff learn techniques for effective collection of patient-reported outcomes (TECPRO)

Optional session on working with culturally and linguistically diverse patient populations

Next TECPRO session with Language curriculum – Fall 2025

To register email procelcore@mskcc.org

Bilingual Competency Program

Language Services, IHCD, & HR

The Bilingual Competency Program (BCP) is a voluntary program that offers bilingual clinicians and staff members an opportunity to assess their ability to communicate in a target language with patients.

Community-Engagement & Language Expertise

Community-Engagement & Language Expertise

Identification and resolution of logistic and structural barriers to research participation by minority patients and community members

Assessment/data analytic methods designed in concert with the community

PRO-CEL Contact

PIs encouraged to contact PRO-CEL Core Facility early in grant/protocol development process

REDCap Consultation Request form on PRO-CEL Intranet Site

https://one.mskcc.org/sites/pub/ski/CoreFacilities/Pages/PRO-CEL-Core-Facility.aspx

Contact: procelcore@mskcc.org

Conclusions

- Lack of diversity in clinical trials in the US
- Multiple barriers to clinical trial enrollment exist, many related to race/ethnicity, preferred language, and social determinants of health
- Possible solutions exist from the literature
- MSK enrollment of underrepresented groups in clinical trials is low
- Some solutions exist at MSK to increase clinical trial enrollment diversity

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