Recruitment and Retention in Cancer Research

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WHAT HAPPENED IN 1993?

On June 10, 1993, Congress passed the NIH Revitalization Act, requiring the inclusion of women in clinical research for the *first* time.

2023 marks 30 years since the passing of this law — but we're still decades behind.

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

April 2022
Clinical/ Medical

Enhancing the participation of diverse populations in clinical trials

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Adequate Representation of Diverse Populations

- Proportion of groups is consistent with representation in catchment area
- Number of minorities is sufficient to allow sub-group analyses
- Enrollment reflects the distribution of disease risk and outcomes

Corbie-Smith et al.

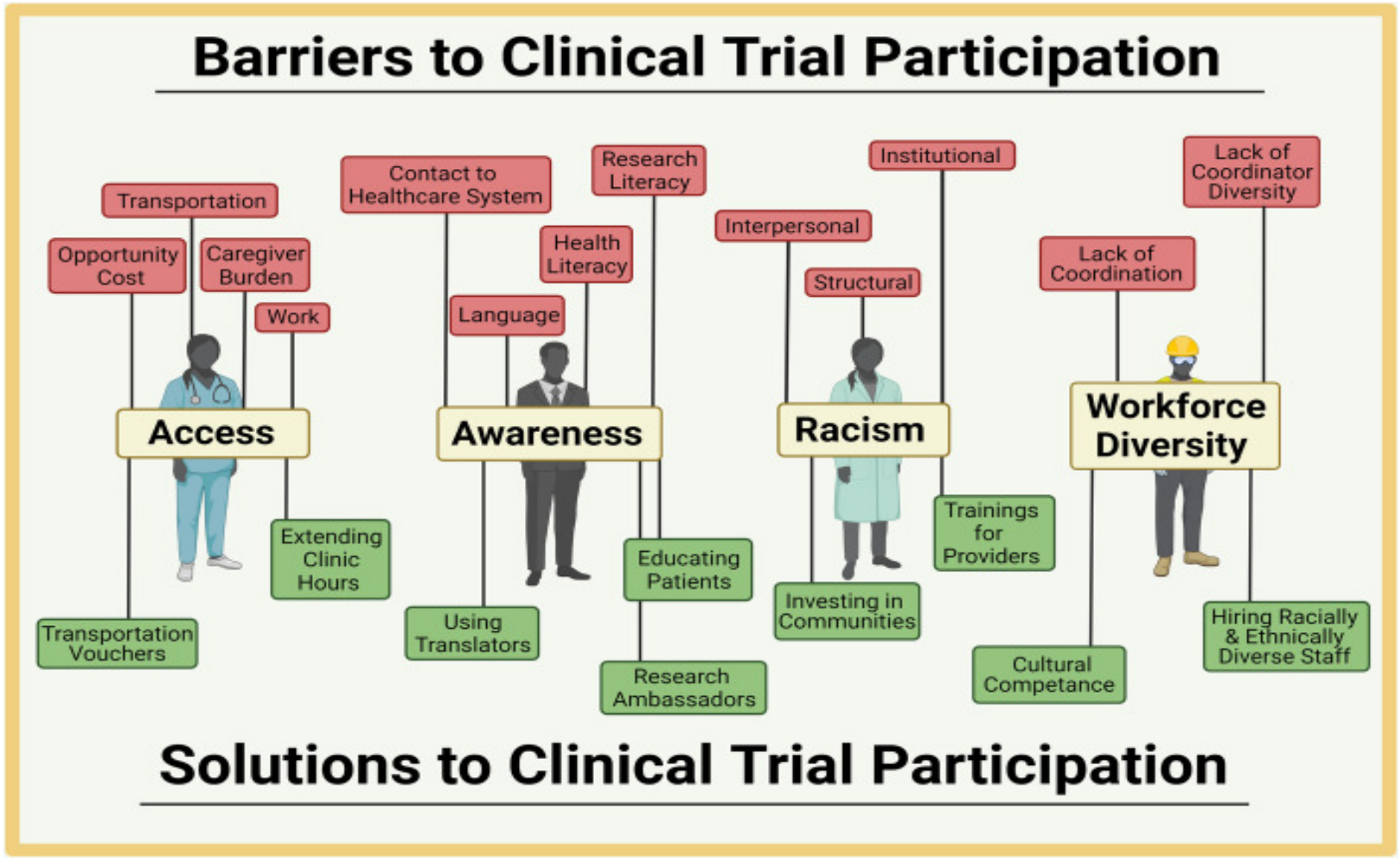
Demographic Trends in NCI-Sponsored Early-Phase Clinical Trials (2000–2023): A Cohort Study

Increased

Enrollment rates for demographic groups	Participation rates were below incidence rates

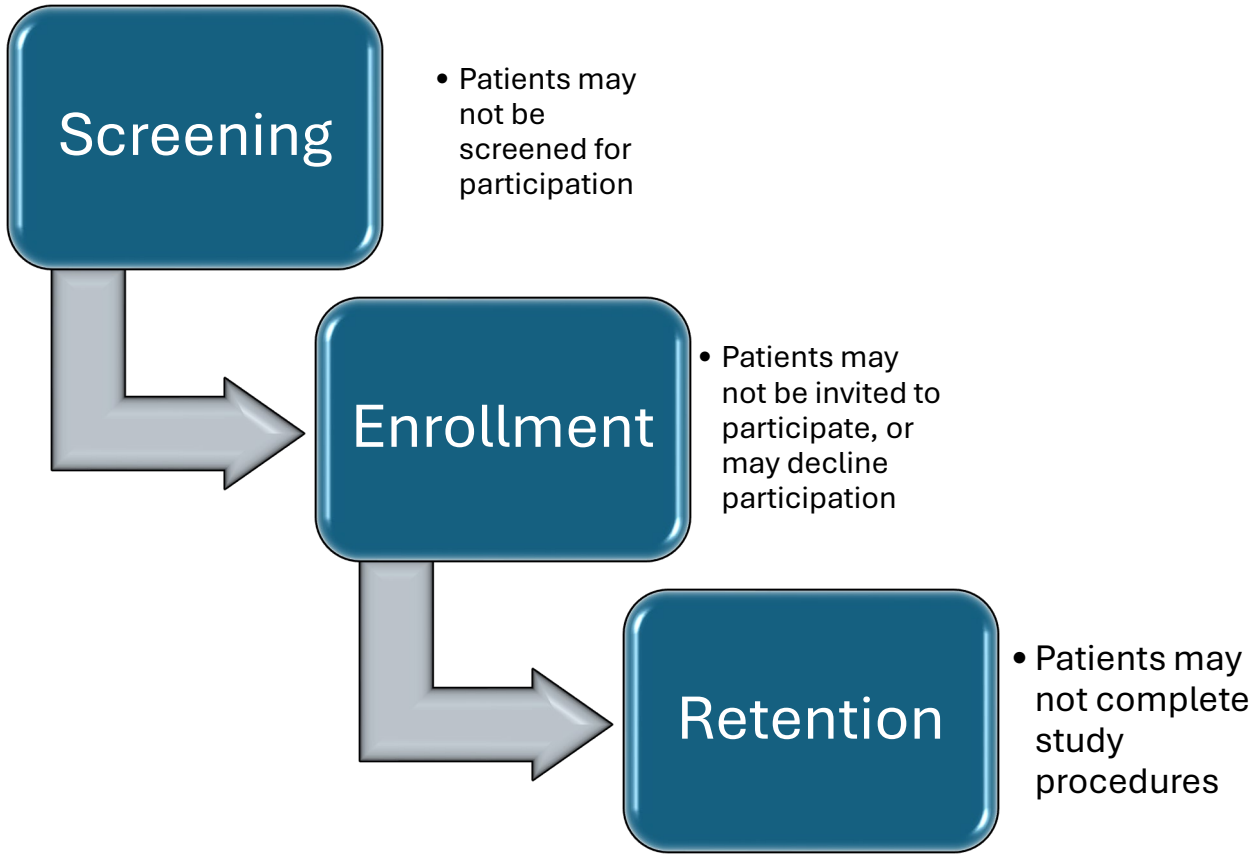
Not representative

Farooq, Sharon, & Takebe. Cancer Discovery, 2025



Reopell L, Nolan TS, Gray DM 2nd, Williams A, Brewer LC, Bryant AL, Wilson G, Williams E, Jones C, McKoy A, Grever J, Soliman A, Baez J, Nawaz S, Walker DM, Metlock F, Zappe L, Gregory J, Joseph JJ. Community engagement and clinical trial diversity: Navigating barriers and co-designing solutions-A report from the "Health Equity through Diversity" seminar series. PLoS One. 2023 Feb 16;18(2):e0281940. doi: 10.1371/journal.pone.0281940. PMID: 36795792; PMCID: PMC9934412.

Inefficiencies in Recruitment and Retention

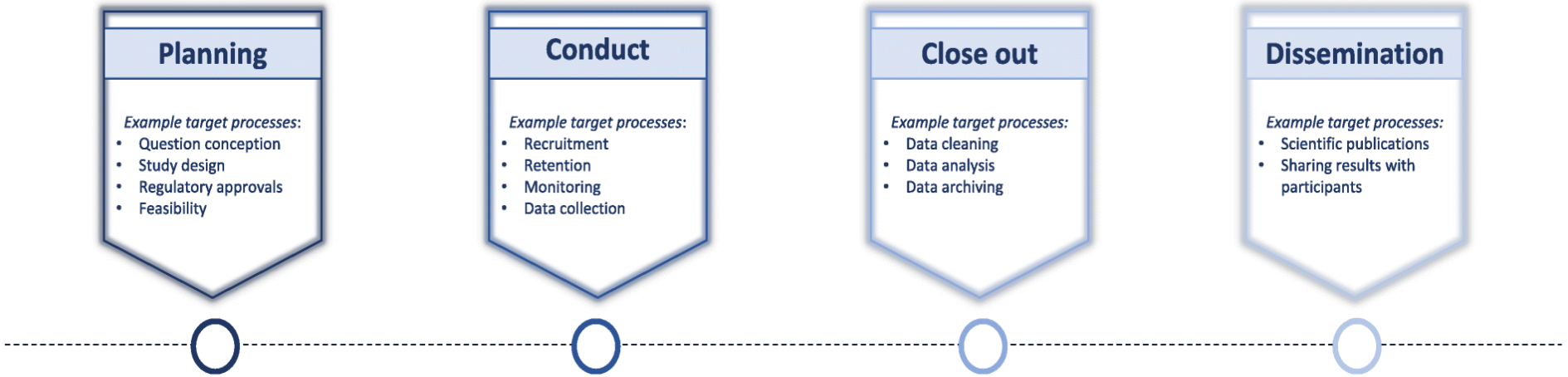


Recruitment and retention are complex

Participation in cancer research is a health care decision

- Understand barriers and facilitators to participation in cancer research
- Develop and implement evidence-based recruitment strategies
- Monitor each phase of the recruitment process
- Evaluate participation outcomes

Behavioral Science in Clinical Trials



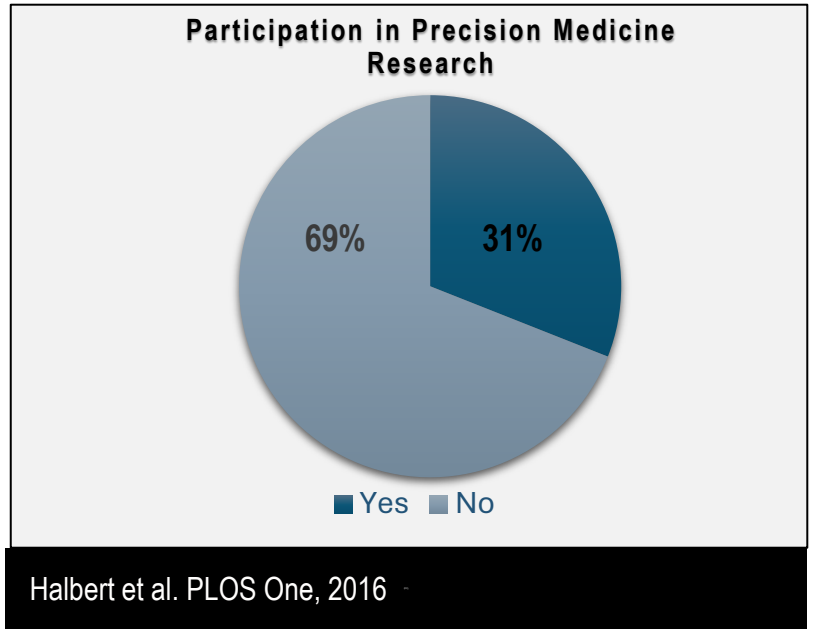
Example process problem	Recruitment of participants	Sharing results with participants at end of trial
Behavioural specification (identifying the problems)	*Use a framework such as AACTT to specify the key behaviours involved in recruitment for further investigation.*	
	Actions: such as clinician screening patients, providing information, informed consent discussion; **Actor**: clinician responsible for recruitment; **Context**: hospital clinic; **Target** of behaviour: potential trial participants; **Time**: throughout the trial.	**Actions**: identifying whether and how participants wish to receive results, disseminating the result to participant at trial end; **Actor**: Chief Investigator and/or Trial Manager and/or Sponsor; **Context**: trial office; **Target** of behaviour: trial participants; **Time**: end of the trial.
Behavioural investigation (diagnosing the problems)	*Several ways to investigate the problem, which may include:*	
	• Conduct behaviourally focussed interviews with health care professionals (and/or patients) to identify salient theoretical domains important to influence (positively or negatively) trial recruitment. • BCT analysis of site training and/or staff and patient information related to recruitment.	• Survey of stakeholders (trial teams, funders, regulators) to understand the main behavioural (individual, collective, organisational) challenges to sharing trial results with participants at the end of a trial
Behavioural solutions (treating the problems)	*Develop targeted behaviour change solutions that incorporate relevant BCTs identified from the previous stages, which ideally would be evaluated and implemented.*	
	• Potential solutions may include tailored training for staff, restructuring the physical environment, incentives or rewards all of which will depend on the diagnosis phase and acceptability of potential solutions to be implemented.	• Potential solutions may include audit of existing practice with follow up feedback that highlights their practice compared with existing standards and/or against other trial teams, and, reward and threats, again all of which will depend on the diagnosis phase and acceptability of potential solutions to be implemented.

Gillies, K., Brehaut, J., Coffey, T. *et al.* How can behavioural science help us design better trials?. *Trials* **22**, 882 (2021). https://doi.org/10.1186/s13063-021-05853-x

African American Participation in Genetics Research

Study Attributes

- Sponsored by government
- Answering Qx
- Data used for current and future studies
- Participants would not receive results



Halbert et al. PLOS One, 2016

Attribute	Importance (% Utility Range)
Receiving results about personal health and general research results	60.17%
Answering questionnaire or providing cheek swab (vs. blood test or tissue biopsy)	16.05%
Receiving results about personal health	14.75%
Receiving information about diagnosis, prognosis, treatment	5.47%
Study sponsored by government (vs pharmaceutical company)	3.14%
Data used for current study only (vs. current and future studies)	0.42%

African American Participation in Cancer Genetics Research

Participation Facilitators	% Likely
Study provided free medication or health care	64%
Study addressed a health condition that was personally relevant	65%
Participation lasted a short period of time	60%
Participation Barriers	**% Unlikely**
Difficulty getting to where the study was being conducted	69%
Not knowing who would be able to obtain their personal information	66%
Lack of study findings being available to participants	60%

McDonald et al., 2014

Transdisciplinary Collaborative Center in Precision Medicine and Minority Men's Health

- Multi-regional consortium
- Translational research on biological, social, psychological, and clinical factors
- Dissemination and implementation
- Data integration

Low Country AHEC
National Black Leadership Initiative on Cancer
Hope Institute, LLC
Southeastern Health Equity Council

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Automatic Trial Eligibility Surveillance Based on Unstructured Clinical Data

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Review

Review

A systematic review on natural language processing systems for eligibility prescreening in clinical research

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Using Electronic Health Records to Support Recruitment

Structured and unstructured data in the electronic health record can be used to pre-screen patients for eligibility to participate in cancer research.

- Determine feasibility for conducting the study
- Identify eligible participants
- Contact potential participants
- Disseminate research findings

Advantages and Disadvantages to Using Electronic Health Records to Support Recruitment

Advantages

- Patient identification based on inclusion and exclusion criteria
- Focus on specific patient characteristics
- Define the denominator and determine response rates

Disadvantages

- Data quality and validation
- Privacy and confidentiality
- Lack of patient response and access to health information technology

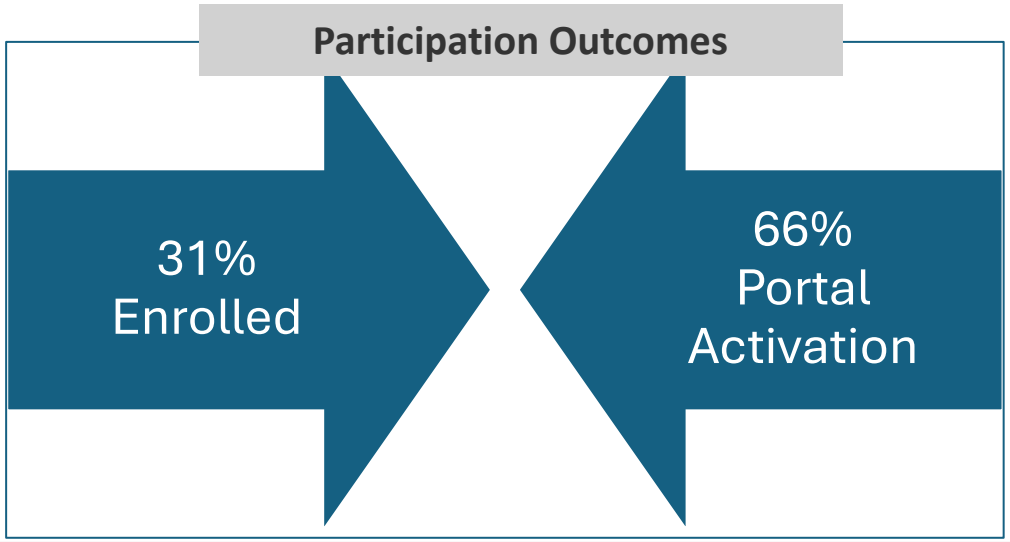
Social Deprivation and Participation in Precision Medicine Research in African American Prostate Cancer Survivors

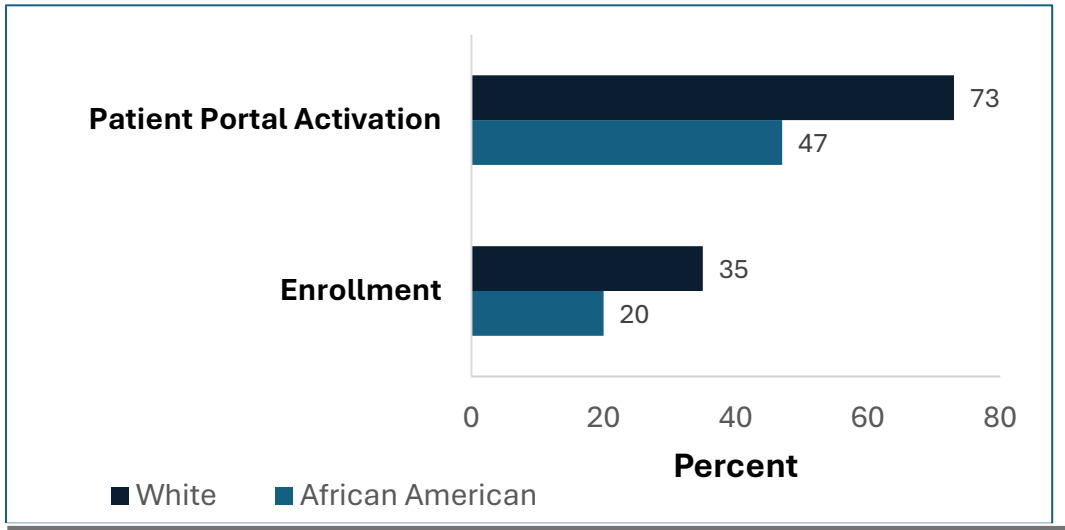
JCO™ CLINICAL CANCER INFORMATICS
An American Society of Clinical Oncology® journal

Defining an Integrated Allostatic Load Index with Immune and Tumor Microenvironment Factors

Participants: Prostate cancer patients identified from biorepository and tissue analysis core at HCC (n=218)

Outcomes: Enrollment in social determinants study and activation of patient portal





Social deprivation associated with a significantly reduced likelihood

Variable	Odds Ratio	95% Confidence Interval
Enrollment	0.70	0.50, 0.98*
Patient portal activation	0.58	0.42, 0.82*

*p between 0.01 and 0.05

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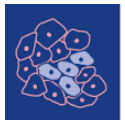
A Systems Approach to Interrogate Gene Expression Patterns among Men in the VA Health Care System

Overall N=60				African Americans n(%) 33 (55%)			Caucasians n(%) 27 (45%)		
	Mean (SD)	Minimum	Maximum	Mean (SD)	Minimum	Maximum	Mean	Minimum	Maximum
Age, Mean +/- SD	65.6 (6.6)	46	76	64.6 (6.6)	46	76	65.8(6.6)	46	75
Blood Pressure, Mean +/- SD	SBP: 137 (18.1) DBP: 82 (8.9)	109 62	183 100	SBP: 137 (18.3) DBP: 83 (8.9)	109 66	183 100	SBP:136 (18.2) DBP: 80 (8.8)	112 62	170 98
Body Mass Index, Mean +/- SD	29.4 (6.2)	14.8	52.1	29.1 (7.5)	14.8	52.1	29.8 (4.1)	22.1	37.4
Vitamin D	30.1 (14.2)	4.8	68.6	26.8 (14.0)	4.8	63.3	34.0 (13.7)	11.1	68.6
Total cholesterol	190 (39.6)	85	271	199.5 (40.6)	85	271	175.6 (34.7)	109	257
HBA1C	5.83 (1.0)	4.1	10	5.9 (1.1)	4.1	10	5.6 (0.9)	4.6	9.2
PSA	7.61 (5.4)	0.56	31.5	8.0 (6.3)	1.7	31.5	7.1 (4.1)	0.56	20.3
Grade	3.7(3.4)	0	9	5.2(3.1)	0	9	1.9(3.0)	0	7
Number positive cores	2.4 (3.3)	0	12	3.8(3.7)	0	12	0.6 (1.1)	0	4



cancers

Hardimann et al., Cancers, 2021

U54 MD010706

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Recruitment and retention are complex

USC CHOICES Lab
Community Health Outcomes, Innovation, Impact, and Equity Studies

American Cancer Society

RALPH LAUREN CORPORATE FOUNDATION

STAND UP TO CANCER

NCI

Thank you!

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