Penn Medicine

Abramson Cancer Center

Cancer Clinical Trials: Two Interventions to Increase Participation Among Underrepresented Groups

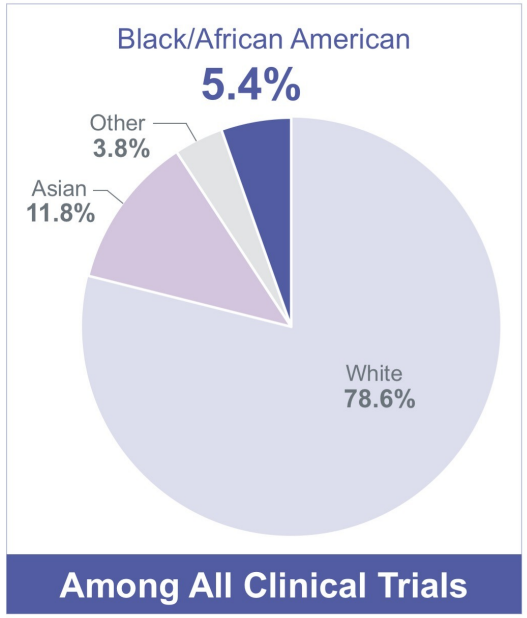
Alexander Auchus

August 18, 2020

Racial Disparities in Cancer Clinical Trials (CCT)

- **In the U.S., African Americans and Latinos comprise 12% and 16% of the U.S. population, respectively, yet each group accounts for less than five percent of trial participants (FDA, 2018).**

Black/African American Clinical Trial Participation



Specific Therapeutic Areas (2015-16)

Black/African American	Black/African American
2.5%	2.74%
Cardiovascular Trials	Oncology Trials

- **White participants represent about 78.6% of all clinical trial participants.**
- **Asian, Black/African American, and other groups represent 11.8%, 5.4%, and 3.8%, respectively.**

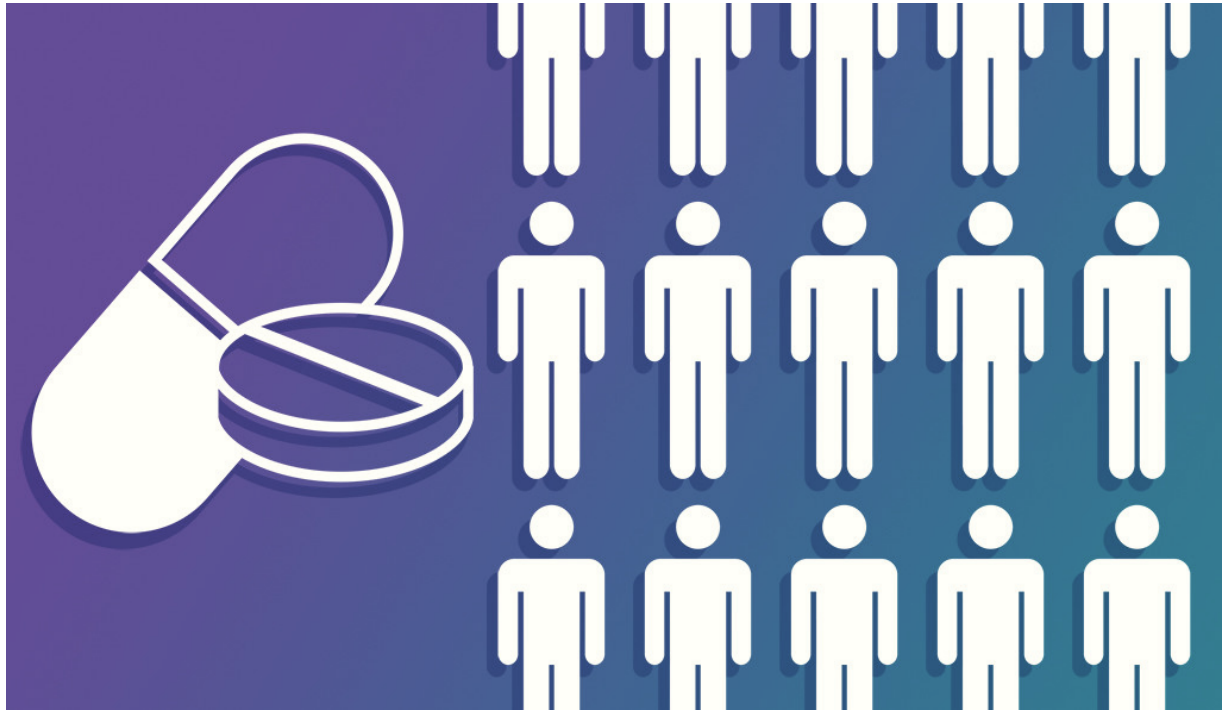
When looking at specific therapeutic areas, Black/African Americans only represent 2.5% cardiovascular and 2.74% of oncology trial participants from 2015-2016 *(FDA Global Trial Participation 2015-16)* despite the prevalence of cardiovascular disease and aggressive cancers in this minority *(Coakley, Fadiran et al. 2012)*.

SANOFI

Source: Sanofi, 2019

Implications of Racial Disparities in Cancer Clinical Trials

- Results from CCTs are not necessarily generalizable
  - Efficacy and safety
- Lack of minority recruitment means slower progress
- CCTs represent access to the most cutting-edge treatments



Causes of CCT Disparities

- Limited access
- Limited knowledge
- Distrust of healthcare system and providers
  - Tuskegee syphilis study
  - Henrietta Lacks
- Out of pocket costs → Lazarex IMPACT
  - Financial Toxicity

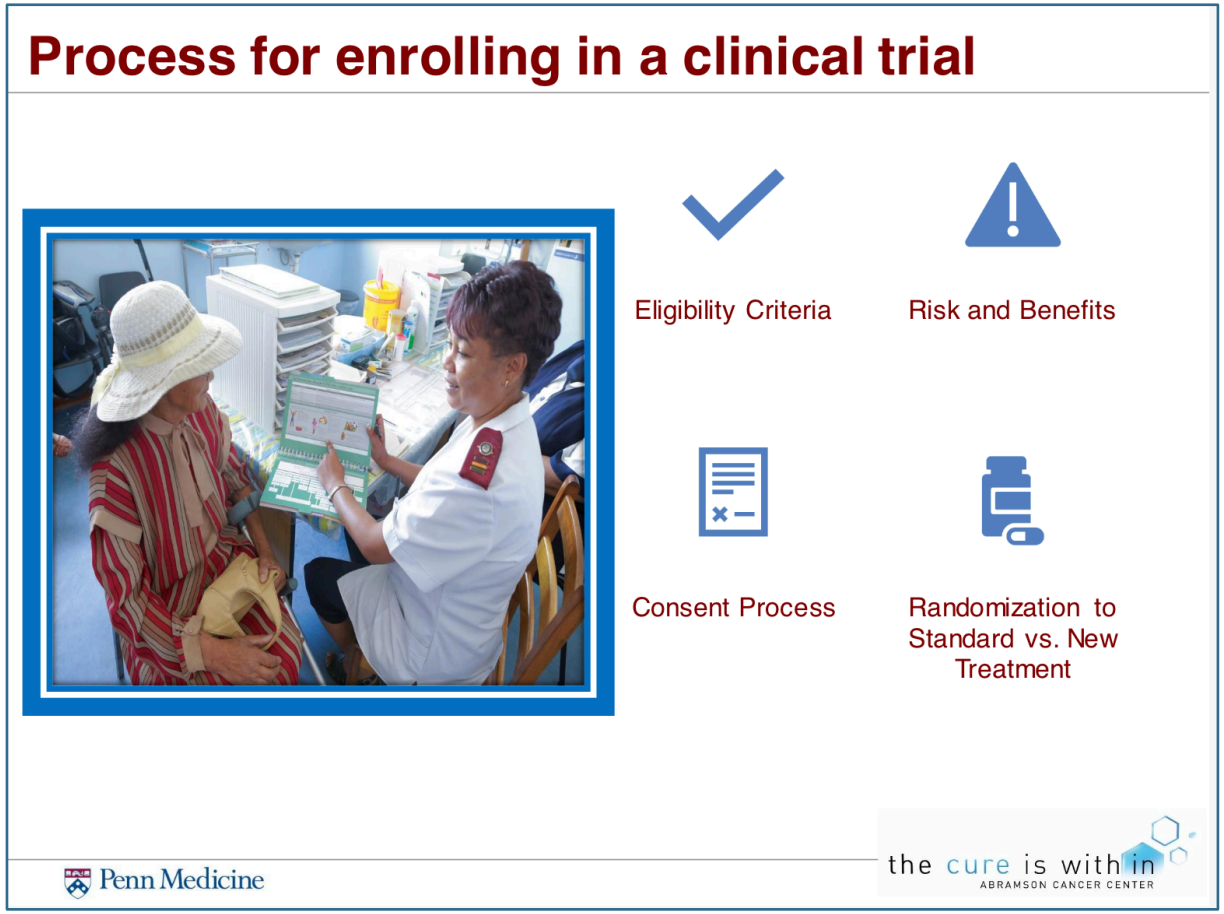
→ ACC Clinical Trials Ambassador Program

Abramson Cancer Center (ACC) Clinical Trials Community Ambassador Training Program

- **Aims:**
  1. **Create a curriculum for lay volunteers to engage in a peer-to-peer educational program with newly diagnosed patient with cancer.**
  2. **Determine feasibility and acceptability of program.**
  3. **Evaluate curriculum for efficacy of CCT education and self-efficacy building.**
     - **Quasi-experimental design (pre-post)**

ACC Training Program Curriculum

- Basics of cancer
- CCT knowledge
  - CCT design and terminology
  - Eligibility criteria
  - History of research abuses
  - Patient protections
  - Importance of minority participation
  - Consent form
  - CCT web resources
- Self-efficacy in educating patients about CCTs
  - Role-playing
  - Practicums



ACC Training Program Study Design

- **Participants**
  - 20 cancer survivors and/or caregivers of patients with cancer from underrepresented communities
- **Methods**
  - Interactive virtual training sessions
- **Measures**
  - Knowledge
    - Multiple choice and T/F assessments
    - Pre-post each session
  - Self-efficacy
    - Likert scale assessments
    - Retrospective pre-post at end of program

Abramson Cancer Center Clinical Trials Ambassador Program Session 3 Questionnaire

08/11/20

Correct responses are **bolded.**

1. What is your Ambassador Number? _____
2. Taking part in the trial is voluntary. (**T**/F)
3. If I had not wanted to participate in a clinical trial, I could have declined to sign the consent form. (**T**/F)
4. Once you enroll in a clinical trial, you can leave the trial at any time without giving a reason. (**T**/F)

ACC Training Program Data Collection and Analysis

- **Data Collection**
  - Online surveys via REDCap
- **Analysis**
  - Pre-post: paired t-tests, ANOVA, ANCOVA

Future Directions ACC Ambassador Program

- Analyze pre-post data
- Refine curriculum
- Publish results
- Implement curriculum at ACC between Sept-Nov 2020
- Measure impact of ambassadors on referrals to CCTs

Lazarex Improving Patient Access to Cancer Clinical Trials (IMPACT)

- **IMPACT,** an evidence-based financial reimbursement program **(FRP)** to help patients and caregivers cover the out-of-pocket travel costs associated with clinical trial participation.
- Borno et al.
  - 42% of patients who declined were not interested in receiving assistance or thought they would not qualify for the program
  - 22% may have been eligible but did not enroll
  - 40% of patients who were enrolled in the FRP and IMPACT study did **not** submit receipts for reimbursement.

Lazarex IMPACT Specific Aims

Aims:

1. To determine if the Lazarex IMPACT FRP improves enrollment rates, retention rates, and racial and ethnic diversity of adult patients with cancer in cancer clinical treatment trials at the Abramson Cancer Center compared to previous rates.

2. To identify the facilitators and barriers to enrollment and to submitting documentation for reimbursement of eligible adult patients in the Lazarex IMPACT FRP.

Lazarex IMPACT Methods

- **Participants**
  - Adult patients with diagnosed cancer who are enrolled in a therapeutic clinical trial at the Abramson Cancer Center, at all University of Pennsylvania hospitals, and are eligible for the Lazarex FRP

- **Study Design: Mixed Methods to Evaluate Dissemination and Implementation of IMPACT Intervention**
  - Quantitative: pre-post comparisons of enrollment, retention, and diversity of CCTs at ACC
  - Qualitative: determine facilitators and barriers of enrollment into the IMPACT program

- **Sample size**
  - 475 over 3 years
  - The initial 125 patients in the first year will participate in the qualitative arm

Lazarex IMPACT Measures

- **Quantitative Measures**
  - CCT enrollment and retention rates of patients eligible for and who participate in the IMPACT program
  - Sociodemographic characteristics of patients eligible for and who participate in the IMPACT program
- **Qualitative Measures**
  - Semi-structured interviews (questionnaires and financial toxicity measures) to determine facilitators and barriers to participation in the Lazarex IMPACT program

Semi-structured Interview #1

1. **Are you enrolled in cancer treatment trial at ACC? If not, why not?**
2. **Were you contacted by the Lazarex Cancer Foundation**? Yes/No.
3. If yes**, Did you enroll in the Lazarex Cancer Foundation IMPACT FRP?** Yes/No
4. If did not complete enrollment, **Is there anything we can do to help you enroll in the program?** List ways patient needs help and offer to contact the Lazarex program for assistance.

Lazarex IMPACT Data Collection and Analysis

- Data Collection
  - Quantitative clinical trial enrollment/retention/sociodemographic data collected through prospective research methods
  - Qualitative data recorded with iPhones and transcribed by third party
- Analysis
  - Quantitative data will be compared to previous data (pre-post) using t-tests, chi-square tests, ANOVA to evaluate intervention efficacy
  - Qualitative data will be analyzed using Nvivo to determine recurrent themes (facilitators and barriers to IMPACT enrollment and use)

Future Directions

- 3 years of implementing IMPACT at ACC
- Analyzing interviews using Grounded Theory Methods of Analysis
- Refine the program and its delivery

Lessons Learned

- **CCT participation disparities**
  - Race, ethnicity, gender, age
  - Henrietta Lacks Enhancing Cancer Research Act of 2019
    - What actions Federal agencies have taken and can take to address barriers to participation in CCTs
- **Training curriculum design**
  - Patient protections continue to evolve
  - Addressing v. ignoring past abuses
- **Questionnaire design**
  - Avoiding bias
  - Does it measure what we want it to measure?
- **REDCap**
- **IRBs**: balancing specificity and vagueness
- **Financial toxicity** poses a significant barrier to CCT participation

Thank You

- LDI SUMR
  - Joanne Levy
- Penn Medicine
  - Dr. Carmen Guerra


Penn Medicine