



Abu Dhabi



Florida



London



Ohio

Disparities and underrepresentation in research access and treatment

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Representation of Minorities and Women in Oncology Clinical Trials: Review of the Past 14 Years

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Table 1. Participants in All Therapeutic Cancer Trials, 2003-2016 (N = 55,689)

| Characteristic | Current Trial Participants | | 1996-2002 Trial Participants* | | 2013 Cancer Prevalence† | 2010 US Census |
|--------------------------------|----------------------------|------|-------------------------------|------|-------------------------|----------------|
| | No. | % | No. | % | % | % |
| Race/ethnicity | | | | | | |
| Non-Hispanic white | 46,431 | 83.4 | 64,355 | 85.6 | 79.0 | 66.0 |
| African American | 3,270 | 6.0 | 6,882 | 9.2 | 10.0 | 12.6 |
| Hispanic | 1,484 | 2.6 | 2,292 | 3.1 | 7.0 | 16.0 |
| Asian/Pacific Islander | 2,982 | 5.3 | 1,446 | 1.9 | 3.3 | 4.8 |
| American Indian/Alaskan Native | 190 | 0.3 | 240 | 0.3 | 0.3 | 0.6 |
| Other | 1,332 | 2.4 | NA | | | |

Race of participants in pembrolizumab trials by cancer site

| Site | Trials | White | Black | Asian | Other | All |
|-----------------|--------|------------|----------|-----------|----------|------|
| Ovary | 5 | 118 | 2 | 7 | 8 | 135 |
| Cervix | 2 | 100 | 2 | 12 | 8 | 122 |
| Uterus | 2 | 61 | 3 | 4 | 10 | 78 |
| Breast | 10 | 1427 | 115 | 451 | 134 | 2127 |
| All gynecologic | 9 | 279 (83%) | 7 (2%) | 23 (7%) | 26 (8%) | 335 |
| All sites | 19 | 1706 (69%) | 122 (5%) | 474 (19%) | 160 (6%) | 2462 |

Enrollment of black patients, expected versus observed

| Site | Incidence per 100 000 | | Expected* black | Observed black | Difference | P value |
|--------|-----------------------|----------------|-----------------|----------------|---------------|---------|
| | White patients | Black patients | | | | |
| Ovary | 10.4 | 8.1 | 1211 | 38 | 32-fold lower | <0.0001 |
| Cervix | 7.3 | 8.3 | 229 | 12 | 19-fold lower | <0.0001 |
| Uterus | 27.2 | 27.5 | 105 | 7 | 15-fold lower | <0.0001 |
| Breast | 125 | 121 | 3048 | 282 | 11-fold lower | <0.0001 |

PACIFIC: A double-blind, placebo-controlled Phase III study of durvalumab after chemoradiation therapy in patients with Stage III, locally advanced, unresectable NSCLC

- Patients with stage III, locally advanced, unresectable NSCLC who have not progressed following definitive platinum-based cCRT (≥ 2 cycles)
- 18 years or older
- WHO PS score 0 or 1
- Estimated life expectancy of ≥ 12 weeks
- Archived tissue was collected

All-comers population

1–42 days
post-cCRT

R

Durvalumab
10 mg/kg q2w for
up to 12 months
N=476

2:1 randomization,
stratified by age, sex,
and smoking history
N=713

Placebo
10 mg/kg q2w for
up to 12 months
N=237

Co-primary endpoints

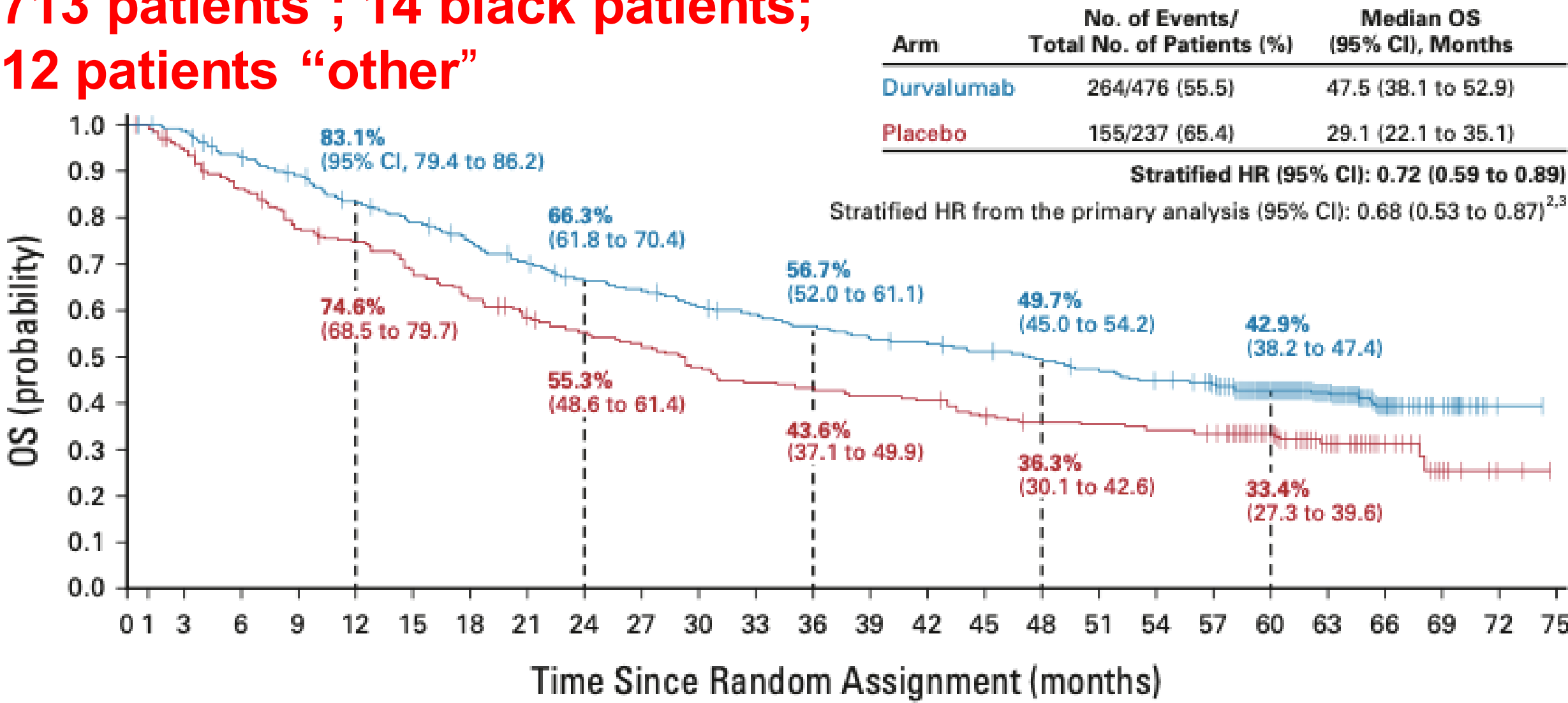
- PFS by BICR using RECIST v1.1*
- OS

Key secondary endpoints

- ORR (per BICR)
- DoR (per BICR)
- Safety and tolerability
- PROs

PACIFIC: 5-yr Survival With Durvalumab After CRT in Stage II NSCLC

713 patients ; 14 black patients;
12 patients “other”



Patient Diversity in ICI Clinical Trials

NSCLC

| | |
|---------------|-----------|
| Checkmate 017 | 90% White |
| Checkmate 057 | 91% White |
| Keynote 001 | 82% White |
| OAK | 71% White |
| Impower 150 | 82% White |
| Keynote 010 | 73% White |

HNSCC

| | |
|---------------|-----------|
| Checkmate 141 | 83% White |
| Keynote 048 | 73% White |

Most cancer-related phase III clinical trials fail to report ethnicity.

Why should there be diversity in clinical trials ?

- **“Common Sense”**

- It should be self-evident that new drugs should be tested in the patient populations in whom they are intended to be used

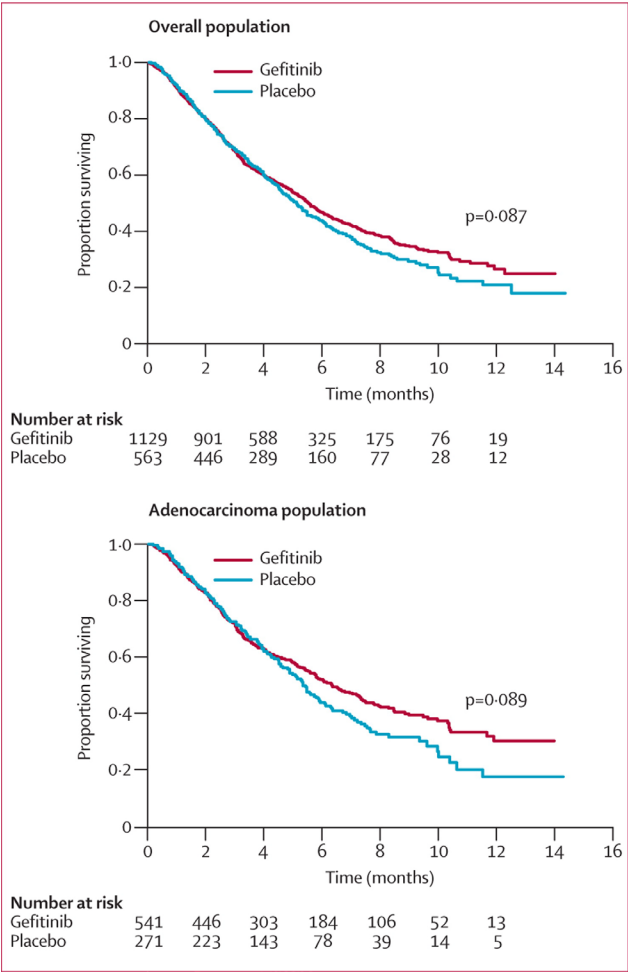
different ethnicities, different sexes, different ages

- **Good Science**

- **Health Equity** – equal access to innovative treatments for all cancer patients

Gefitinib vs Placebo (ISEL)

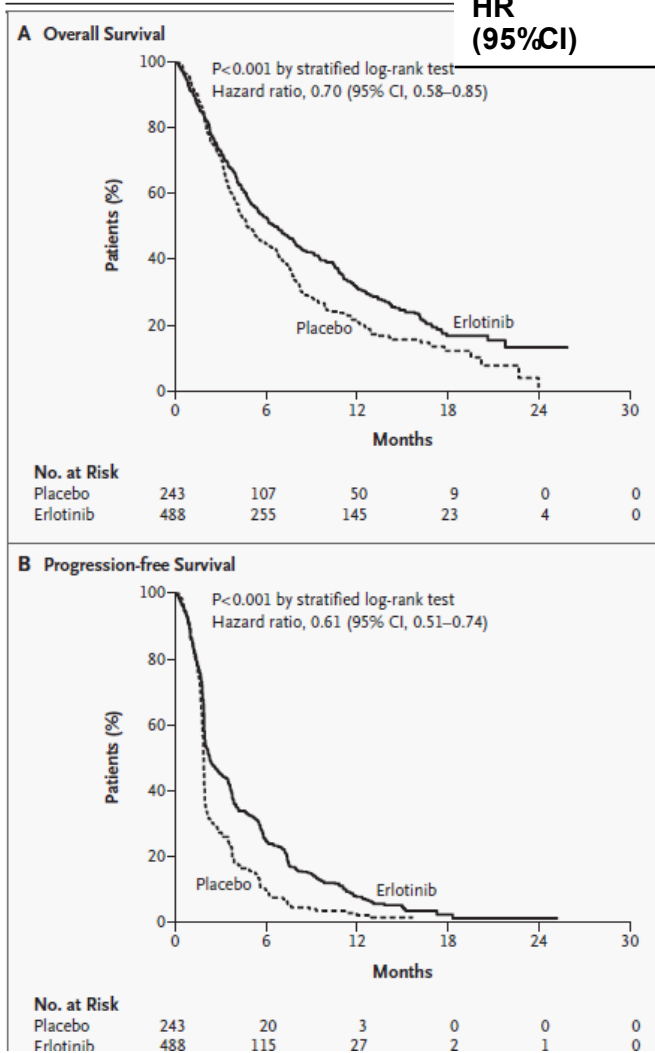
| | Gefitinib | Placebo |
|------------|------------------|---------|
| MST | 5.6 m | 5.1 m |
| HR (95%CI) | 0.89 (0.77-1.02) | |
| | P = 0.0871 | |



Thatcher N et al. Lancet 366:1527-1537, 2005

Erlotinib vs Placebo (BR21)

| | Erlotinib | Placebo |
|------------|------------------|---------|
| MST | 6.7 m | 4.7 m |
| HR (95%CI) | 0.70 (0.58-0.85) | |
| | P < 0.0001 | |



Shephard F et al. N Engl J Med 353: 123-32, 2005

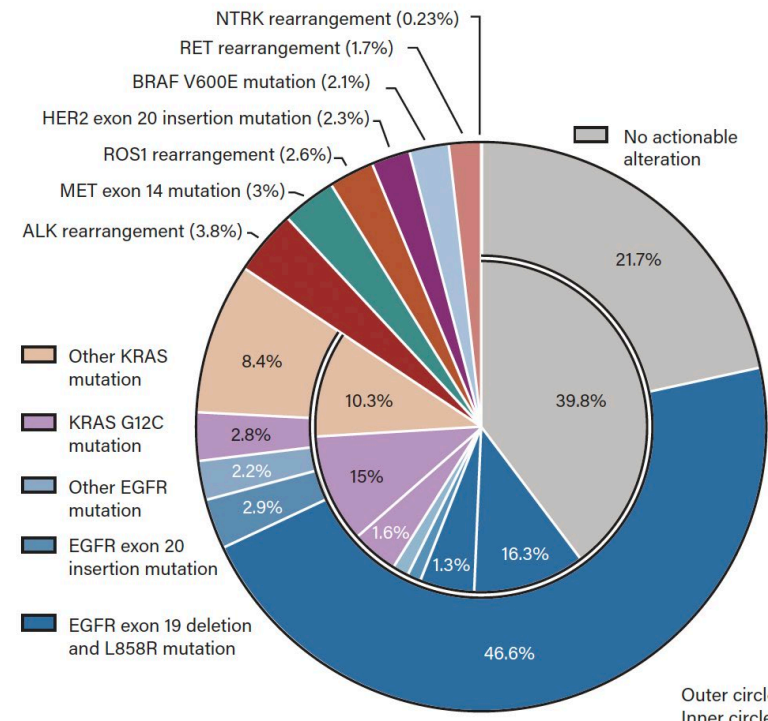


Figure 2-1. Frequency of oncogenic drivers in NSCLC (Source: Tan and Tan 2022,¹ copyright © 2022, by the American Society of Clinical Oncology. Published by Wolters Kluwer. All rights reserved.)

What are some of the reasons for this inequity ?

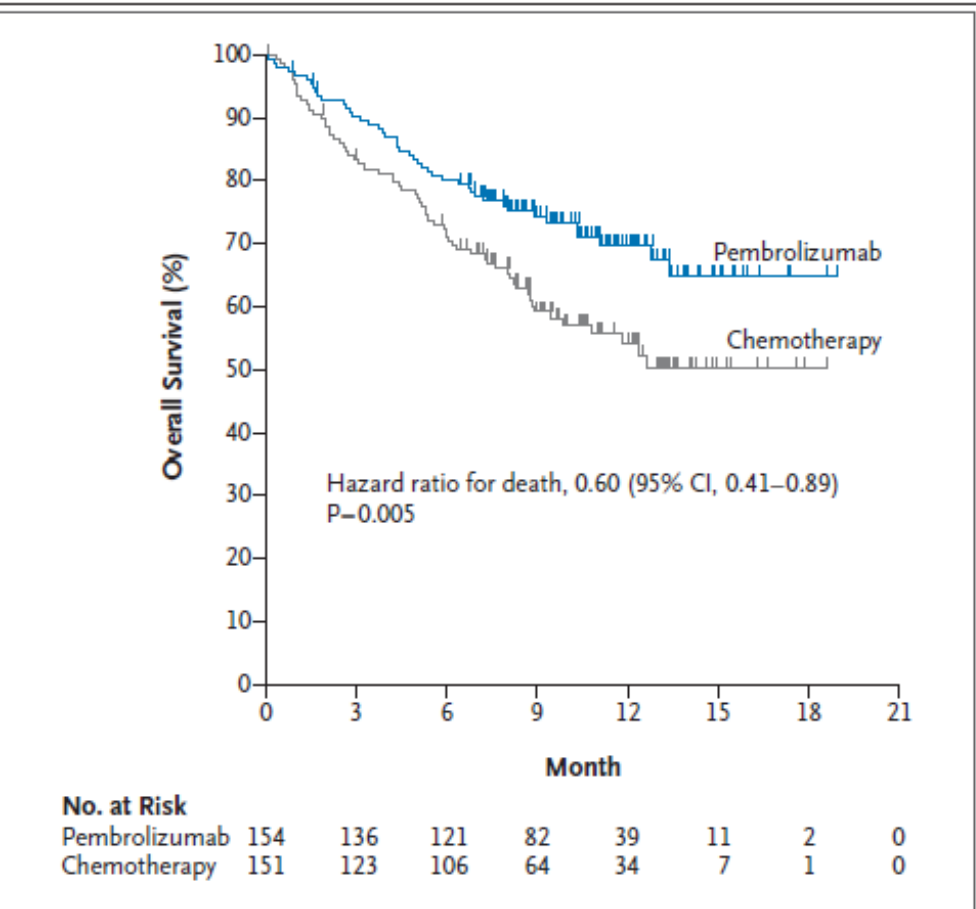
- Socio-economics
- Access – real barriers, and perceived barriers
- Inappropriate clinical trials
- Complexity of trials
- Unconscious bias of health care providers
- Distrust of the health care system

• How do we fix this ?

- Appropriate Clinical Trials – there should be equipoise
- Build Trust
- Workforce Diversity – “our caregivers should look like us”
- Re-engineer clinical trials (real world data, pragmatic trials)

Pembrolizumab vs Chemotherapy

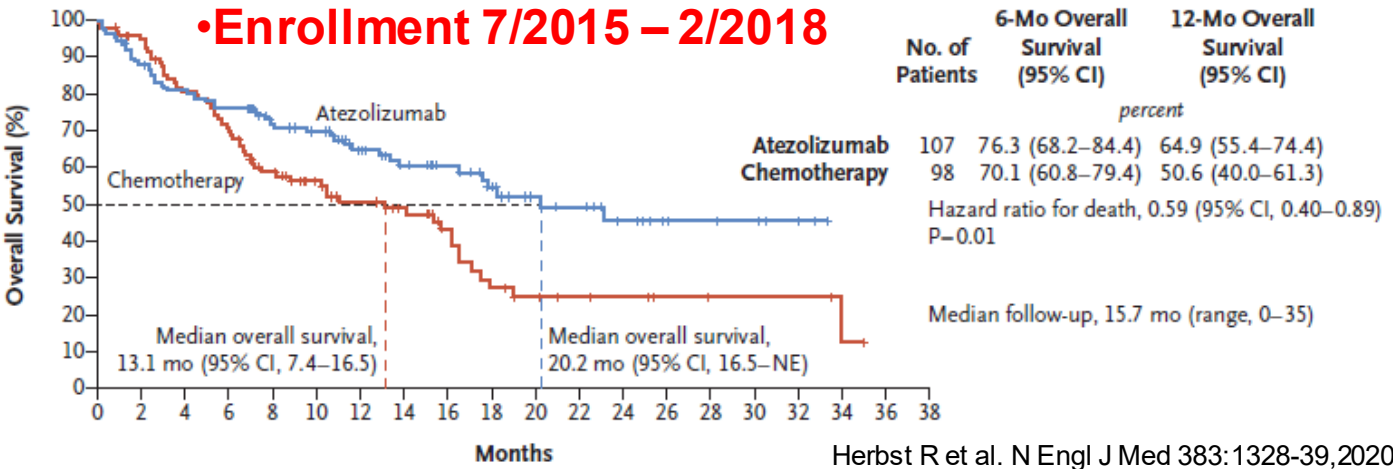
mOS 30m vs 14.2m HR 0.63



- Pembrolizumab accelerated approval October 21, 2015
- Full approval October 24, 2016

Atezolizumab vs Chemotherapy

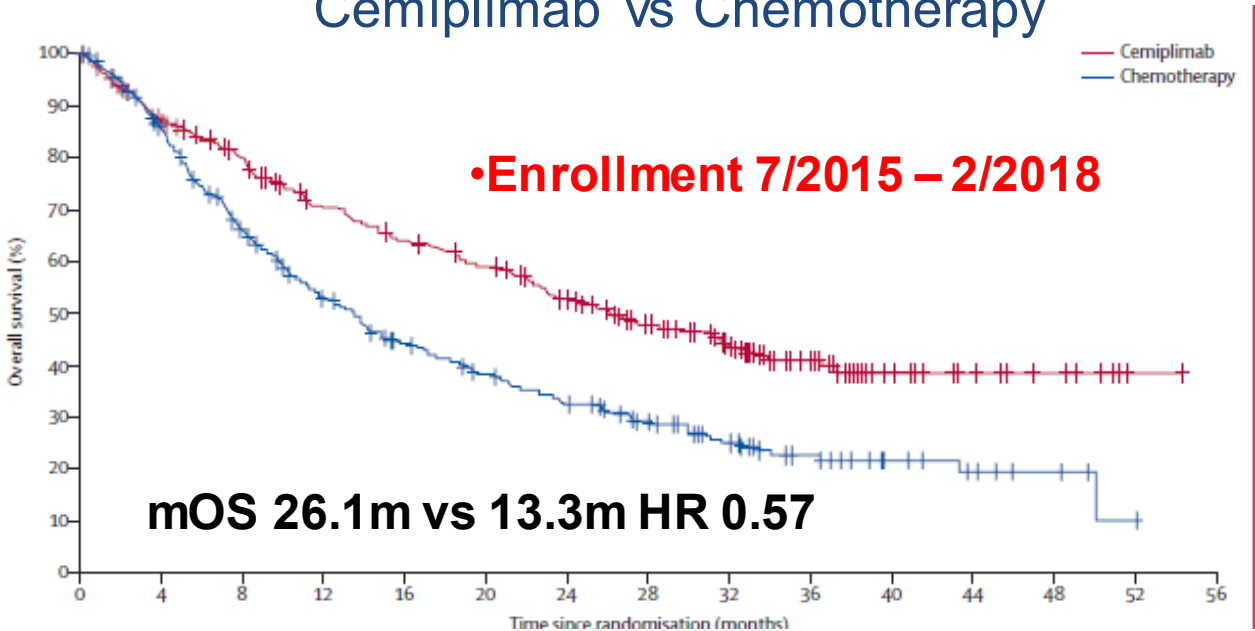
•Enrollment 7/2015 – 2/2018



Herbst R et al. N Engl J Med 383:1328-39,2020

Cemiplimab vs Chemotherapy

•Enrollment 7/2015 – 2/2018



Building Trust : Cleveland Clinic Taussig Cancer Center

Community Outreach and
Patient Navigation



Taussig Cancer Center Community Outreach and Patient Navigation

Evidence-based approach to understanding which communities and/or populations are impacted by health disparities

Zip code analysis

- Cancer incidence rates
- Late stage disease
- Overall survival
- Social determinants of health
- Urban vs. Rural

Research and Documentation

- Community Health Needs Assessments (CHNAs)
- State of Ohio Cancer Control Plan (Ohio Dept. of Health)



Community Outreach Programs

•Women's Health

- HPV
- Colorectal
- Breast
- Lung

•Men's Health

- Prostate
- Colorectal
- Lung

•Population-Based

- LGBT
- Hispanic
- Faith-Based (SCIIT)
- Veterans
- Disabled
- Undocumented immigrants/refugees

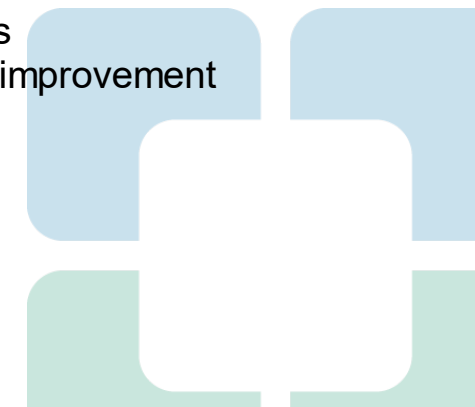
•Access

- Tobacco Cessation
- Medical Home

•Research

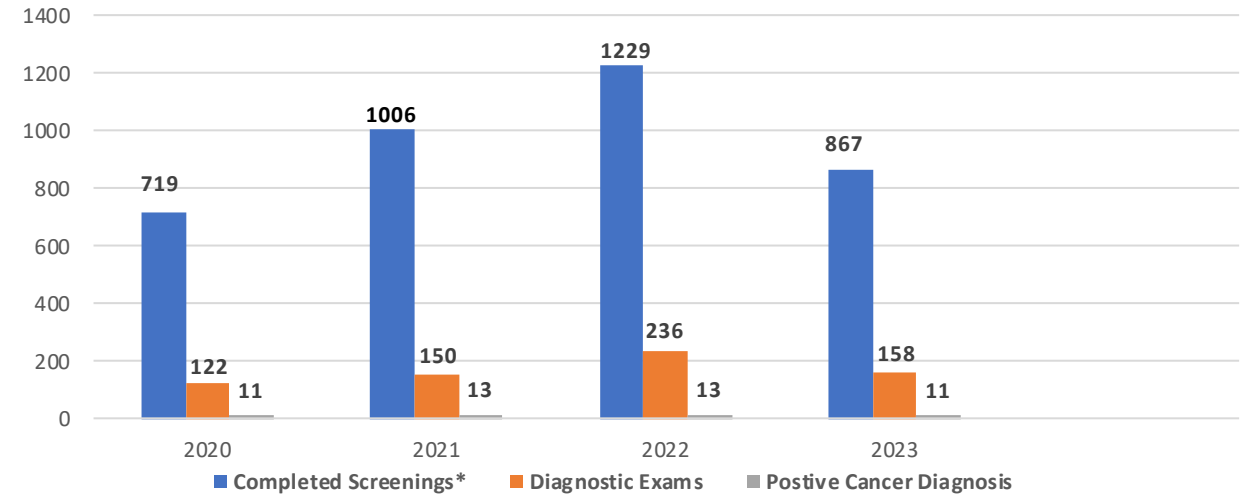
- Surveys
- Quality improvement

What we don't have on this list is Clinical Trials !!!!



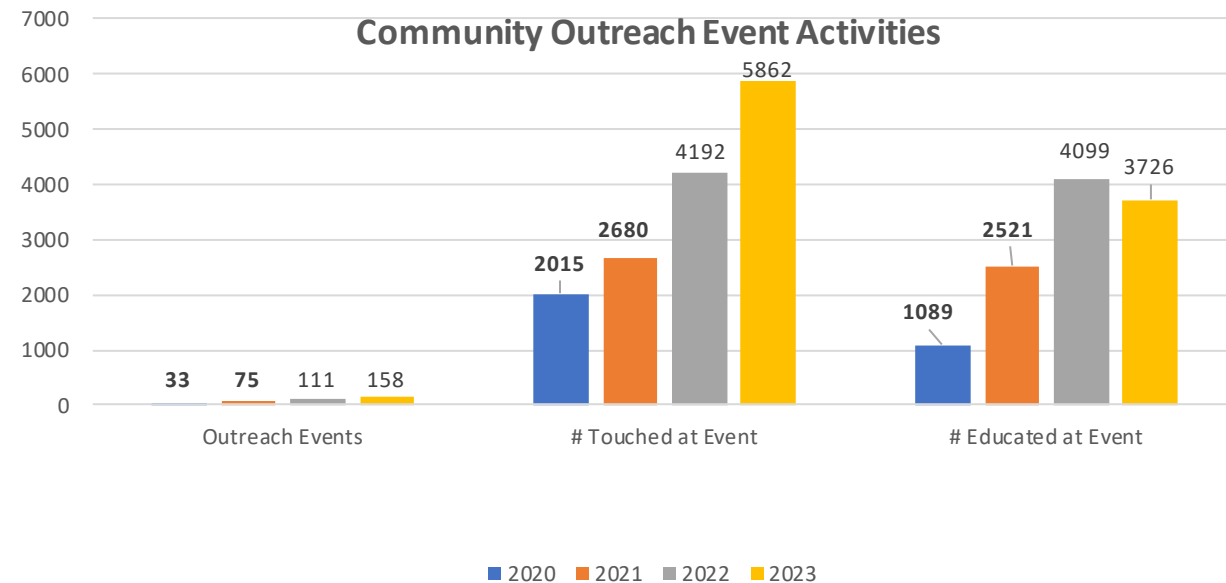
Community Outreach Events and Completed Screenings

Community Outreach Completed Screenings and Exams*



*Data is based on female population

Community Outreach Event Activities



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- Our providers should look like our population
 - Workforce diversity

Clinical Trials Workshop for Minority Physicians : Coral Gables FL, 2014



Clinical Trials Workshop for Minority Physicians : Pomona CA, 2015



Clinical Trials Workshop for Minority Physicians : Ft Lauderdale FL, 2016



Robert A. Winn Diversity in Clinical Trials:Design and Implementation of Clinical Trials Workshop in partnership with the American Association for Cancer Research November 15-19, 2023 | Hilton La Jolla Torrey Pines | La Jolla, CA



Every life deserves world class care.

THANK YOU !

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