

Breast Cancer: Inclusive Research Tactics to Improve Patient Diversity

Leah Peters; Senior Clinical Operations Lead, Genentech

BIO Clinical Trial Diversity Roundtable
January 31, 2023

Astefania: An Ongoing Phase III Clinical Trial Investigating Kadcylla + Tecentriq in Patients with HER2-Positive eBC with Residual Disease after Neoadjuvant Therapy

Measures Set up to Encourage Diversity and Inclusion



Patient Support

- ICFs, ePROs in multiple languages to support diversity within a country.
- Mobile nursing and telemedicine to support rural populations.
- Exploring a wellness (meditation & yoga) app for the patients on study.



Support for the cost of trial participation

- Transport, accommodation and meals reimbursement for clinic visits (via pre-loaded CliniCard).
- Funding of childcare and petcare.
- Also exploring compensation for loss of earnings.



Study Documents

- More inclusive eligibility criteria: HIV patients allowed.
- eCRF adapted to include all FDA race and ethnic groups (first time for Roche/Genentech).



Local country strategies

- Pilot study for US site alliance network & Diversity & Inclusion initiative in UK (AIR UK) to broaden trial access by Geography, Ethnicity and Socio-Economic factors & removing barriers to participation.



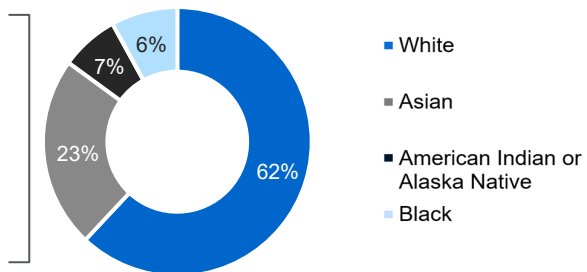
Country Participation

- Country participation informed by underserved populations (eg Uganda, Kenya & India) as well as incidence of breast cancer to position the study to recruit across racial & ethnic groups

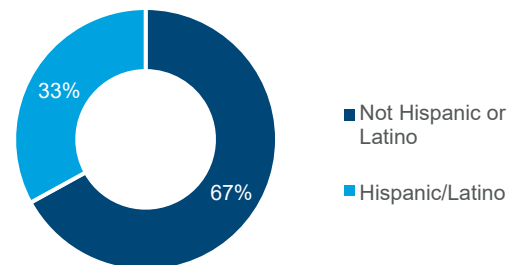
Breast Cancer Trial Diversity

Historical Roche/Genentech trial participation (globally)

By Race

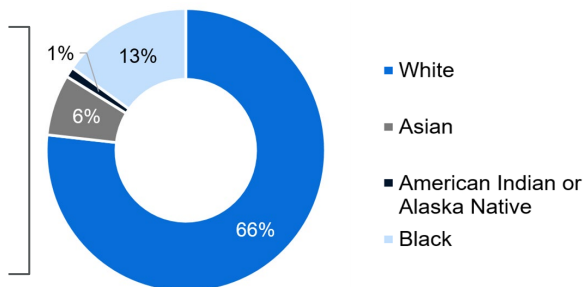


By Ethnicity

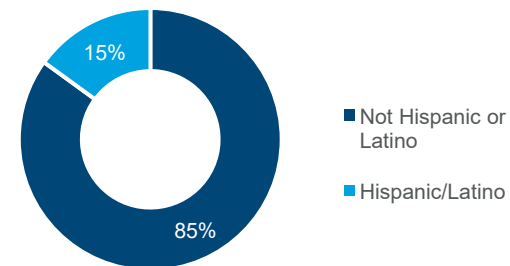


Breast Cancer incidence in the US

Breast Cancer US INCIDENCE BY RACE



Breast Cancer US INCIDENCE BY ETHNICITY



(n = 13,978 Patients, 43 Trials, 43% non-Hispanic White)

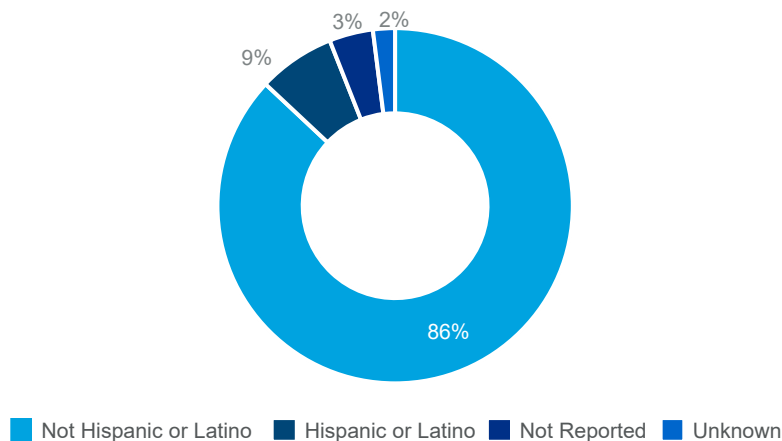
Astefania: A Phase III Clinical Trial Investigating Kadcyła + Tecentriq in Patients with HER2-Positive eBC with Residual Disease after Neoadjuvant Therapy



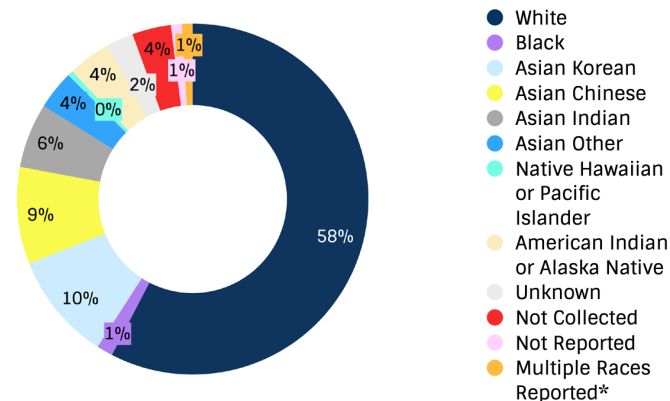
Current status:

- 636/1700 patients enrolled (37% enrollment completed)
- 287/310 sites activated, including 41/50 in the US, 176/189 in Europe, 14/14 in LATAM, 3/3 in Africa, 46/47 in Asia, 7/7 in Oceania

Breakdown of Ethnicity in Astefania Study



Breakdown of race in Astefania Study



*5 subjects reported American Indian or Alaskan Native and White
4 subjects reported begin Black or African American and White

What went well/didn't go well

- The offering of a broad array of translated patient-facing materials and reimbursement of patient costs were successful tactics to increase inclusion of a broader patient population.
- Uptake of decentralized trial delivery tactics such as mobile nursing and eConsent was lower than anticipated. Timing of the study was such that it was initiated when COVID-19 lockdowns were still in place, thus patients were unable or hesitant to utilize these services.

What is needed to improve representation

- More training for investigators and site staff on unconscious bias
- More investigators and site staff that match the representation of patients we want to recruit
- A way to improve access to US patients who have the disease, but because they do not have insurance, they often perceive this as a barrier and do not present to healthcare professionals for treatment