An EYEWITNESS to Successful Diversity in Antiretroviral Switch Studies

P047

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Key Takeaways

- **EYEWITNESS is a phase 3b study evaluating switching to dolutegravir/lamivudine (DTG/3TC) from bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in people with HIV-1 aged ≥50 years who are virologically suppressed and was designed with diversity at its core**
- **Diversity-oriented strategies were integrated into study planning, feasibility, site selection, startup, and recruitment to meet diversity targets of ≥30% for age ≥65 years, female sex assigned at birth, and Black or African American race, and ≥10% for Hispanic or Latinx ethnicity**
- **All diversity targets were exceeded, demonstrating the achievement of diversity in clinical trials is attainable with proactive planning and implementation of tailored strategies during study development**

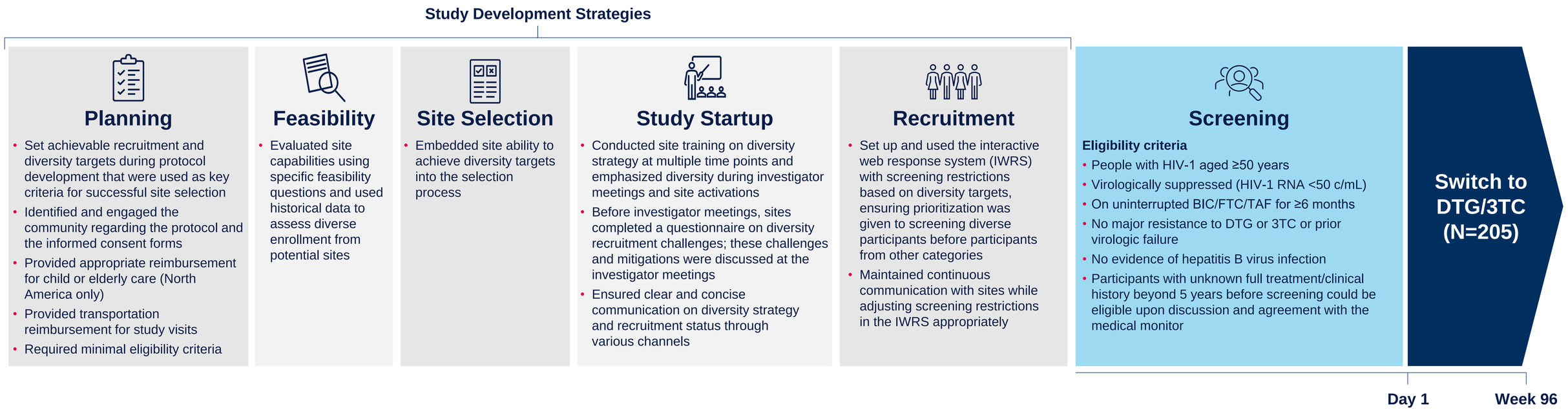
Introduction

- Achieving diversity has long been a challenge in HIV clinical trials, preventing adequate assessment of treatments across all affected populations[1,2]
  - Aligning clinical trial recruitment to epidemiologic prevalence is important given that demographic differences are known to influence therapeutic response[3,4]
- The EYEWITNESS study (NCT05911360) was designed with diversity at its core to dismantle this obstacle to equitable research opportunities, consistent with the aims of ViiV Healthcare and GSK Clinical Trial Diversity initiatives and commitments[1,4]
- DTG/3TC has demonstrated high virologic efficacy and a good safety profile across subgroups by age, sex, and race[5-7]
- EYEWITNESS aims to further enrich data available for DTG/3TC among underrepresented groups, with study enrollment targeting older adults, women, and individuals identifying as Black or African American, or as Hispanic or Latinx—groups who have historically faced systemic barriers to research participation[2]
- Here, we describe the recruitment results and strategies that facilitated achieving these goals

Methods

- EYEWITNESS is a phase 3b, multicenter, open-label, single-arm study evaluating the efficacy, safety, and tolerability of switching to DTG/3TC from BIC/FTC/TAF in people with HIV-1 aged ≥50 years who are virologically suppressed
- This ongoing study is being conducted at 56 sites across 12 countries; enrolled participants were switched to DTG/3TC on Day 1 and will be followed up to 96 weeks
- Diversity targets were set at ≥30% for age ≥65 years, female sex assigned at birth, and Black or African American race, and ≥10% for Hispanic or Latinx ethnicity with a total planned enrollment of 200 participants
- Diversity-oriented strategies were embedded in study planning, feasibility, site selection, startup, and recruitment (Figure 1)

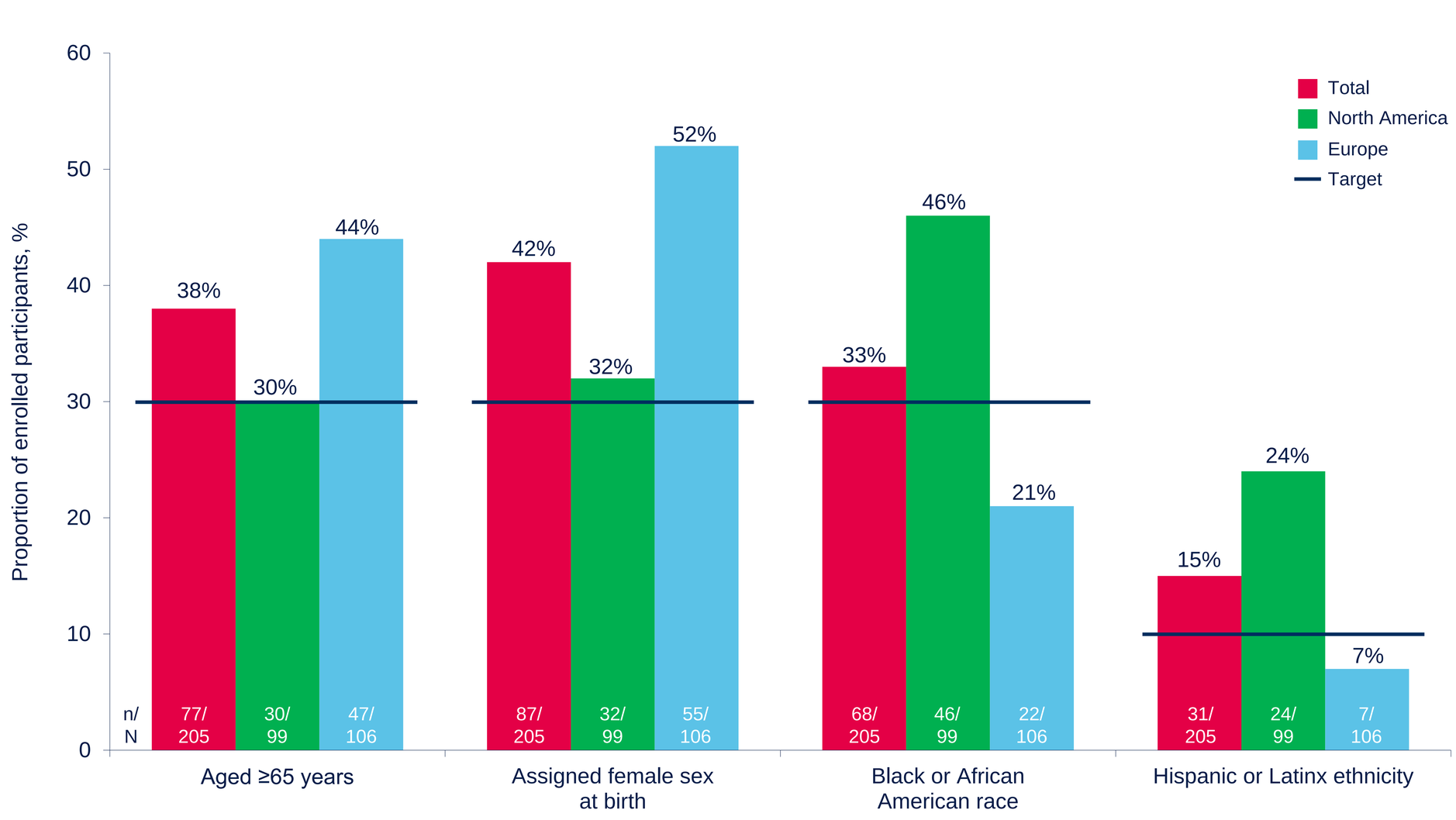
Figure 1. EYEWITNESS Study Design Including Key Strategies Implemented to Achieve Enrollment Diversity Targets



Results

- Recruitment lasted from July 7, 2023, to February 16, 2024, with 265 participants screened and 205 enrolled
  - Ambitious diversity targets did not impact planned/expected recruitment timelines
- All diversity targets were exceeded, with 38% of participants aged ≥65 years, 42% assigned female sex at birth, 33% identifying as Black or African American, and 15% identifying as Hispanic or Latinx (Figure 2)
  - Demographics of participants recruited were generally consistent across North America and Europe, though lower proportions of enrolled participants in Europe identified as Black or African American or as Hispanic or Latinx
- Feedback from study sites indicated that the strategic approach to diverse enrollment was well received

Figure 2. Summary of Demographic Characteristics of Enrolled Participants



Conclusions

- The successful enrollment of a remarkably diverse study population in EYEWITNESS demonstrates the importance of proactive planning and implementation of tailored strategies to achieve diversity in clinical trials
- Such efforts are crucial to ensure treatments address the often unmet needs of all people with HIV-1

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