An EYEWITNESS to Successful Diversity in Antiretroviral Switch Studies

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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 race⁵⁻⁷
- 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 participation²
- 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

Study Development Strategies



Planning

- Set achievable recruitment and diversity targets during protocol development that were used as key criteria for successful site selection
- Identified and engaged the community regarding the protocol and the informed consent forms
- Provided appropriate reimbursement for child or elderly care (North America only)
- Provided transportation
- reimbursement for study visits Required minimal eligibility criteria

Feasibility

Evaluated site capabilities using specific feasibility questions and used historical data to assess diverse enrollment from potential sites

✓× === **Site Selection**

Embedded site ability to achieve diversity targets into the selection process



Study Startup

- Conducted site training on diversity strategy at multiple time points and emphasized diversity during investigator meetings and site activations
- Before investigator meetings, sites completed a questionnaire on diversity recruitment challenges; these challenges and mitigations were discussed at the investigator meetings
- Ensured clear and concise communication on diversity strategy and recruitment status through various channels



Recruitment

- Set up and used the interactive web response system (IWRS) with screening restrictions based on diversity targets, ensuring prioritization was given to screening diverse participants before participants from other categories
- Maintained continuous communication with sites while adjusting screening restrictions in the IWRS appropriately



Eligibility criteria

- People with HIV-1 aged ≥50 years
- Virologically suppressed (HIV-1 RNA <50 c/mL) On uninterrupted BIC/FTC/TAF for ≥6 months
- No major resistance to DTG or 3TC or prior
- virologic failure No evidence of hepatitis B virus infection
- Participants with unknown full treatment/clinical history beyond 5 years before screening could be eligible upon discussion and agreement with the medical monitor



Day 1

Week 96

Results

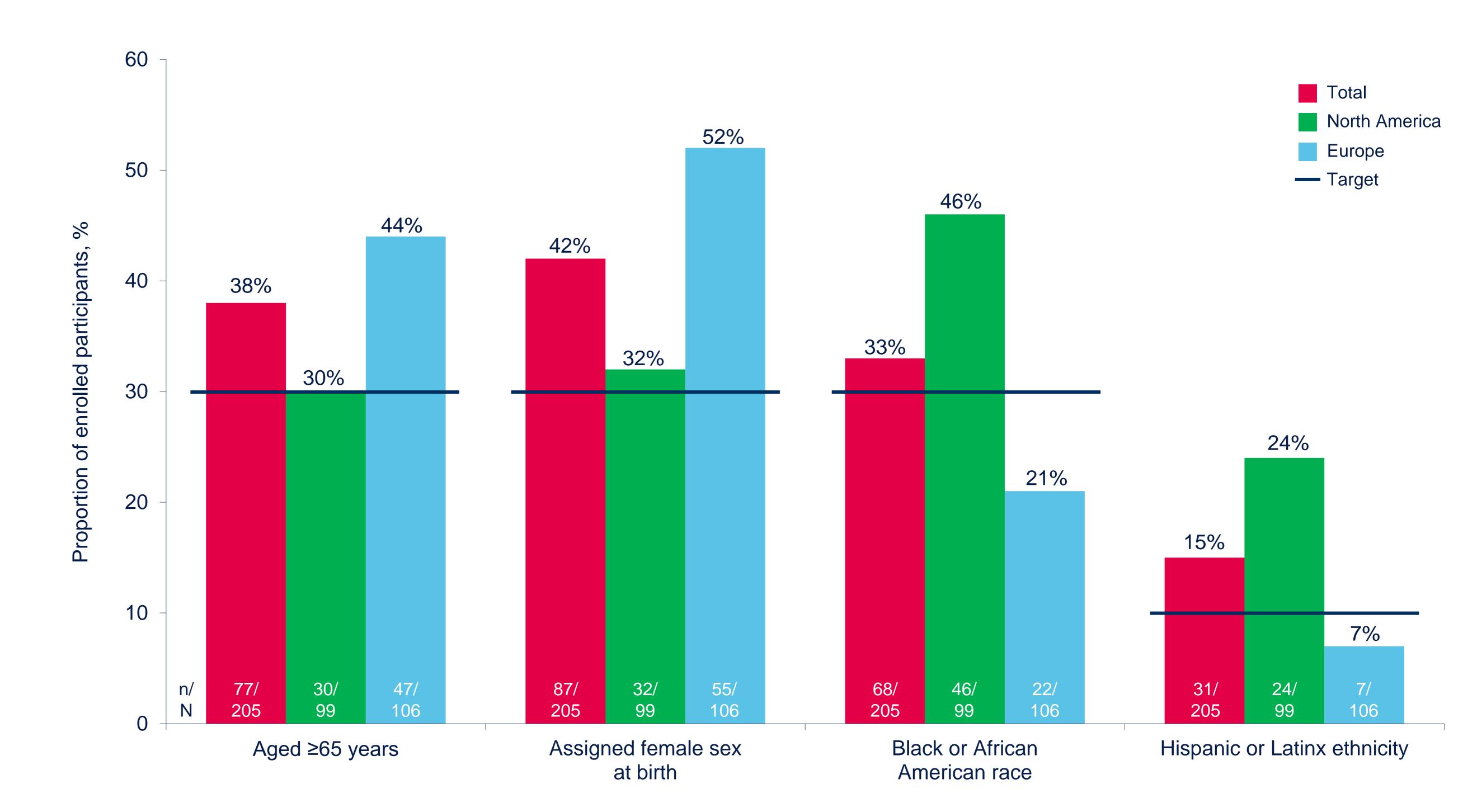
- Recruitment lasted from July 7, 2023, to February 16, 2024, with 265 participants screened and 205 enrolled
- Ambitious diversity targets did not impact planned/expected recruitment timelines
- All diversity targets were exceeded, with 38% of participants aged ≥65 years, 42% assigned female sex at 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

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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Figure 2. Summary of Demographic Characteristics of Enrolled Participants



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