



Investor education event: **Clinical trial diversity**

Alberto Fernandez and Dr. Kimberly Smith

Speakers



Alberto Fernandez

Senior Vice President,
Global Clinical
Operations



Dr Kimberly Smith

Senior Vice President,
Head of R&D
– ViiV Healthcare



Frannie DeFranco

Investor Relations
Director

Agenda

1. Introduction
2. The importance of clinical trial diversity
3. Supporting industry efforts to improve representation
4. ViiV case study: long-acting HIV prevention
5. Q&A

Why inclusive research matters

- Our ambition is to positively impact the health of more than 2.5 billion people
- Diversity, Equity and Inclusion are central to our purpose of getting ahead of disease together
- A scientifically appropriate representation in clinical research is critical for advancing our understanding of new medicines and vaccines to ensure they have the biggest impact on patients
- Representing the patient populations impacted by different diseases in our clinical trials enables our data to represent real-world outcomes for patients



Food and Drug Omnibus Reform Act of 2022

Example of related regulation change

- In December 2022, the Food and Drug Omnibus Reform Act was enacted in the US
- This legislation requires a 'Diversity Action Plan' for all pivotal studies (typically phase III) of new drugs and medical devices
- This requirement will be formalised in the coming years. However, in practice FDA already expects submission of plans
- Next steps:
 - GSK to participate in trial diversity workshop to share experience
 - Formalisation of regulatory requirements



GSK's journey with clinical trial diversity

The last 15 years

Where we were

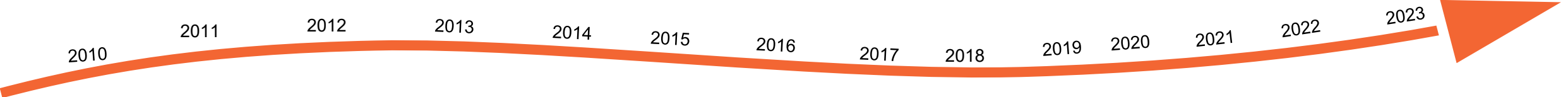
- *Shingrix* preferential approval put at risk and narrowly granted due to registered objections of insufficient minority representation in clinical studies
- Additional phase III study required for *Benlysta* to provide better representation among prevalent Black / African American women with Lupus

What we implemented

- Clinical Trial Diversity team actively working within Clinical Operations
- Appointed dedicated Clinical Trial Diversity Lead
- Invested in Global Demographics & Diversity team headcount for greater impact

Where we are now

- Near real-time diversity monitoring and per study diversity plans based on epidemiology are making clinical trial diversity “Business-As-Usual”
- Early planning for patient-centric engagement across clinical trials
- First FDA Diversity Action Plan compliant program at GSK



2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023

Understanding the challenges and initiatives

The last 5 years



Patient eligibility

Validated
epidemiology and
health equity
hierarchy leading to
increased eligibility,
enrolment, and
representation



Access to clinical trials

Expanded sites into
under-represented
populations
to enroll patients that
represent the disease



Regulatory environment

Created diversity
plans to represent
real-world
patient disease
demographics



Limited trust

Delivered trials
in communities
that were
under-represented
through community
capability building
and decentralisation



Provider bias

Improved ability to
recruit and retain
diverse patient
through standard site
training worldwide

A large, flowing orange shape that starts wide on the left and tapers to a thin line on the right, creating a sense of movement and depth.

GSK study on clinical trial diversity

Supporting industry efforts to improve representation in clinical trials



GSK research on clinical trial diversity

Published in '*Clinical Trials: Journal of the Society for Clinical Trials*'

The need

Trials should optimally reflect the real-world populations of the disease.

Our approach

To evaluate how the demographics of our clinical trial participants (2002-2019) compared to or varied from the US Census.

Our findings

The results demonstrate that using real-world disease epidemiology data, rather than the traditional benchmark of US Census Bureau race and ethnicity data, would increase the potential success rate of clinical trial enrolment reflecting the populations affected by different diseases.

What's next

We now use epidemiologic data for our clinical trials, allowing us to set more accurate trial enrolment goals, resulting in more demographically balanced, diverse, and representative clinical trials. This will also enable a better understanding of drug safety and efficacy per demographic group.

Find the study [here](#)

2022+ ESG KPI for clinical trial diversity

Commitment: Enhance recruitment of diverse patient populations

Performance metric definition	Status	Metric	Achievements
2022			
% of phase III trials initiated in 2022 that will have proactive protocols in place designed to enroll appropriately diverse trial participants, consistent with the disease epidemiology, to be able to assess the clinical needs of those most burdened by the disease under study	Achieved	At least 75% of studies have diversity plans in place	Exceeded with 100% completion by 31 December 2022
2023			
% of phase III trials initiated in 2023 that will have proactive plans in place designed to enroll appropriately diverse trial participants, consistent with the disease epidemiology	On track	100% of target achieved or likely to be achieved by 31 December 2023	

Collaborating with others to achieve better health outcomes for all



A large, flowing orange shape that starts wide on the left and tapers towards the right, creating a sense of movement and depth.

Clinical trial diversity at ViiV Healthcare

HPTN 083 and 084 studies for long-acting pre-exposure prophylaxis



ViiV Healthcare's clinical trial diversity vision and mission

Vision

No one left behind in our research and development

Mission

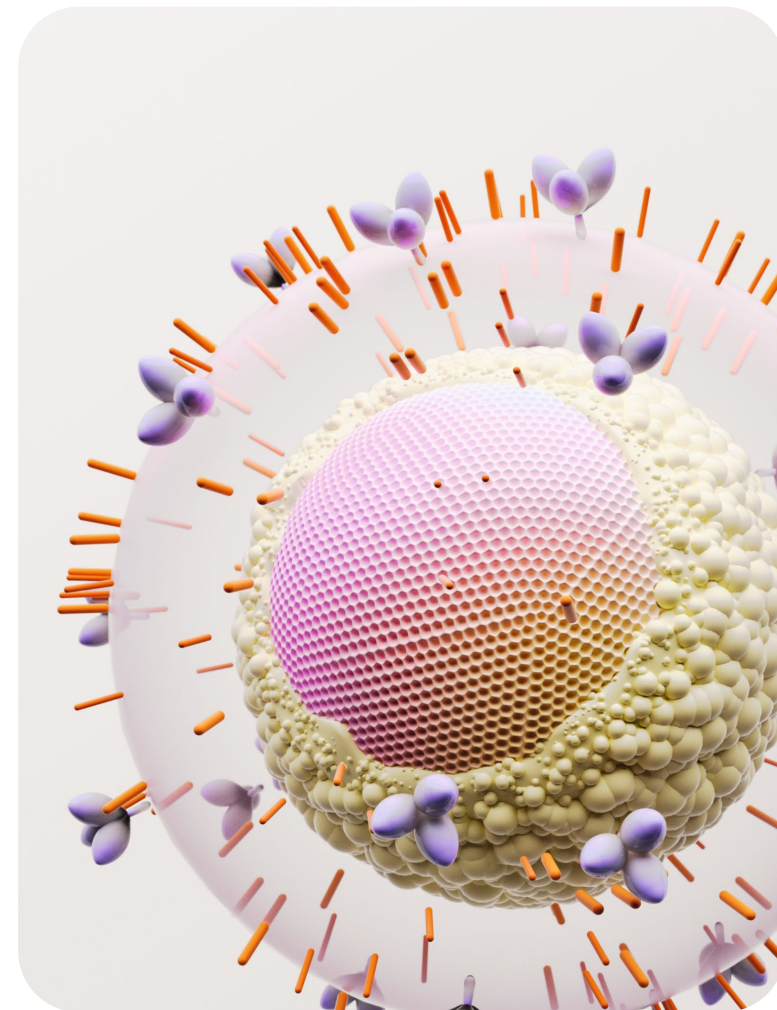
We include diverse populations in our clinical trials so that all people impacted by HIV are represented to ensure no one is left behind

Greater understanding of how the drug works

Broader participant and provider experience

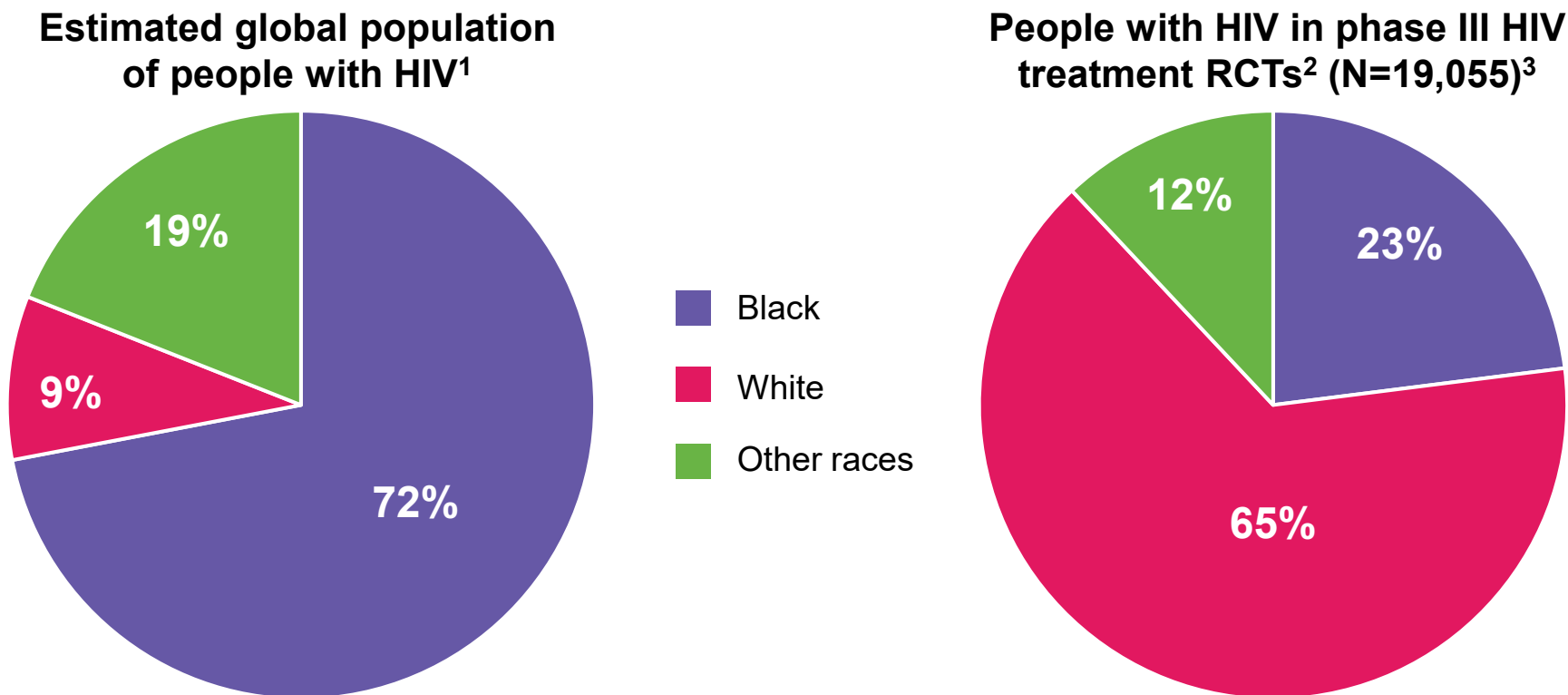
Responsive to community, provider and regulatory interest

Redress past deficiencies



In HIV clinical trials, **Black individuals** are underrepresented relative to the overall global population of people with HIV

People living with HIV in the global population and HIV clinical trials by race

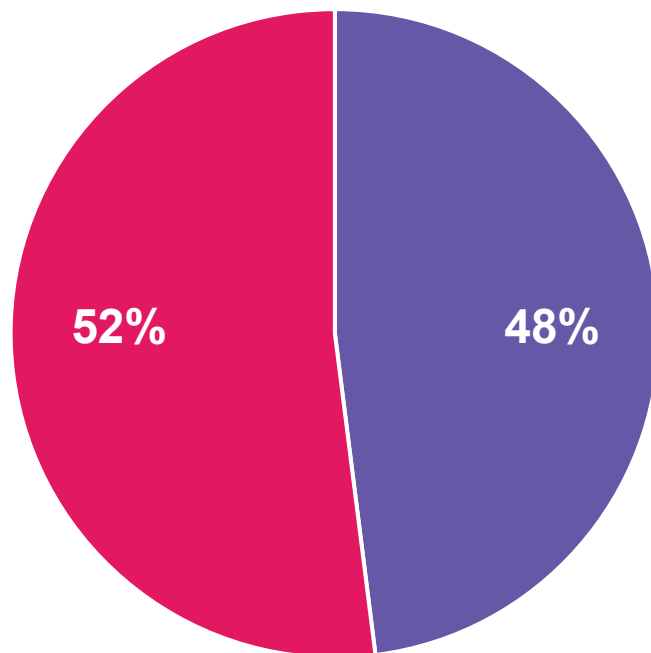


1. Data from 2018 UNAIDS statistics. 2. Randomised controlled trial 3. Data from 24 global phase III HIV treatment RCTs.
Pepperrell et al. *J Virus Erad.* 2020;6:70-73.

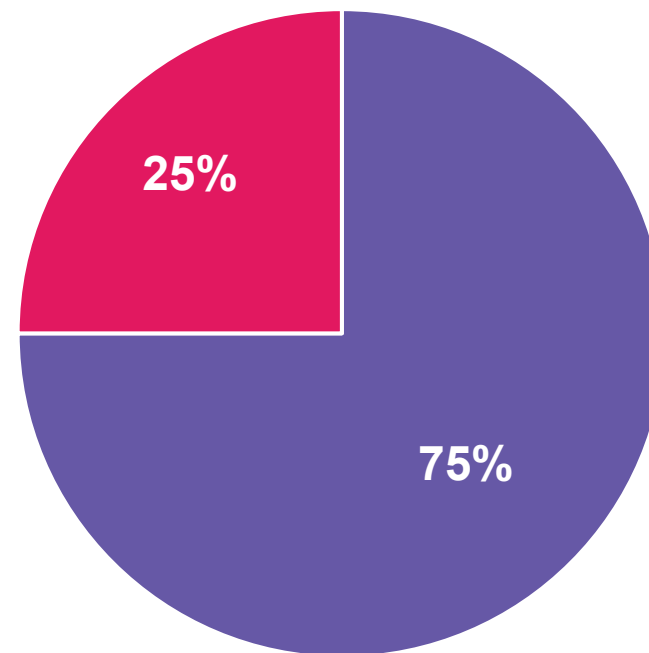
In HIV clinical trials, **women** are underrepresented relative to the overall global population of people with HIV

People living with HIV in the global population and HIV clinical trials by sex

Estimated global population of people with HIV¹



People with HIV in phase III HIV treatment RCTs² (N=19,055)³



■ Male
■ Female

1. Data from 2018 UNAIDS statistics. 2. Randomised controlled trial 3. Data from 24 global phase III HIV treatment RCTs.
Pepperrell et al. *J Virus Erad.* 2020;6:70-73.

Barriers to HIV clinical trial participation

Barriers among racial/ethnic minorities and women include^{1,2}

HIV stigma

eg, concerns of status disclosure

Mistrust in the medical system

eg, fears of being experimented on

Accessibility

eg, cost, language barriers, transportation

Medication concerns

eg, side effects, lack of efficacy

Opportunity

eg, not being asked to participate

1. Bass et al. *AIDS Patient Care STDS*. 2020;34:399-416. 2. Namiba et al. *Therapeutic Advances in Infectious Diseases* 2022;9:20499361221075454.

The global picture for HIV prevention

- Cabotegravir long acting (Cab LA): the first LA injectable for PrEP¹, administered every 2 months. Approved in US, Australia, Zimbabwe and South Africa, with other submissions pending
- HPTN 083/084: first studies to compare the efficacy of Cab LA to daily oral PrEP¹
- HPTN 083: 4,570 cisgender MSM² and TGW³ who have sex with men, at 43 sites/8 countries
- HPTN 084: 3,200 cisgender women at 20 sites/5 countries in Africa
- 50% of US enrollees in 083 were Black MSM², creating the largest interventional trial of BMSM ever completed
- Data shows **3x** superiority in men, **9x** superiority in women in reducing HIV incidence compared to oral PrEP^{1,4}



- **~1.5m** new cases of HIV worldwide each year⁴
- **58%** of new infections are in sub-Saharan Africa⁴
- **63%** of new infections in sub-Saharan Africa are in young women and adolescent girls⁴
- ViiV signed a voluntary licence agreement with MPP⁵ for Cab LA for PrEP¹ and joined a global health coalition to help expedite access

1. Pre-exposure prophylaxis 2. Men who have sex with men 3. Transgender women 4. UNAIDS factsheet 5. The Medicines Patent Pool

Summary

- Appropriate representation in clinical research is critical for advancing medicines and vaccines and ensuring maximum impact for patients
- GSK is committed to ensuring clinical trials reflect diverse demographics of the patients impacted by the disease under study
- We exceeded our 2022 ESG KPI for clinical trial diversity
- There's more to do, but GSK is well-positioned for pending regulatory requirements
- We'll continue to collaborate with others to achieve a shared goal of better health outcomes for all



Q&A

GSK

Q&A housekeeping

- Q&A will be moderated using the “raise hand” function
- When you are selected to ask a question, you will be promoted to speaker
- Once promoted to speaker, please turn on your video, and come off mute
- Before asking your question, please say your name and institution
- If we run out of time, please submit your questions using the Q&A function

Thank you!

Something to look forward to

**Coming
up next**

Topic

Antimicrobial Resistance (AMR)

Details

AMR has been recognised by the World Health Organization as one of the top ten threats to global public health. In this session, a panel of GSK experts will provide insights into how we are getting ahead of AMR.