6th June 2023

Investor education event:
Clinical trial diversity

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Speakers

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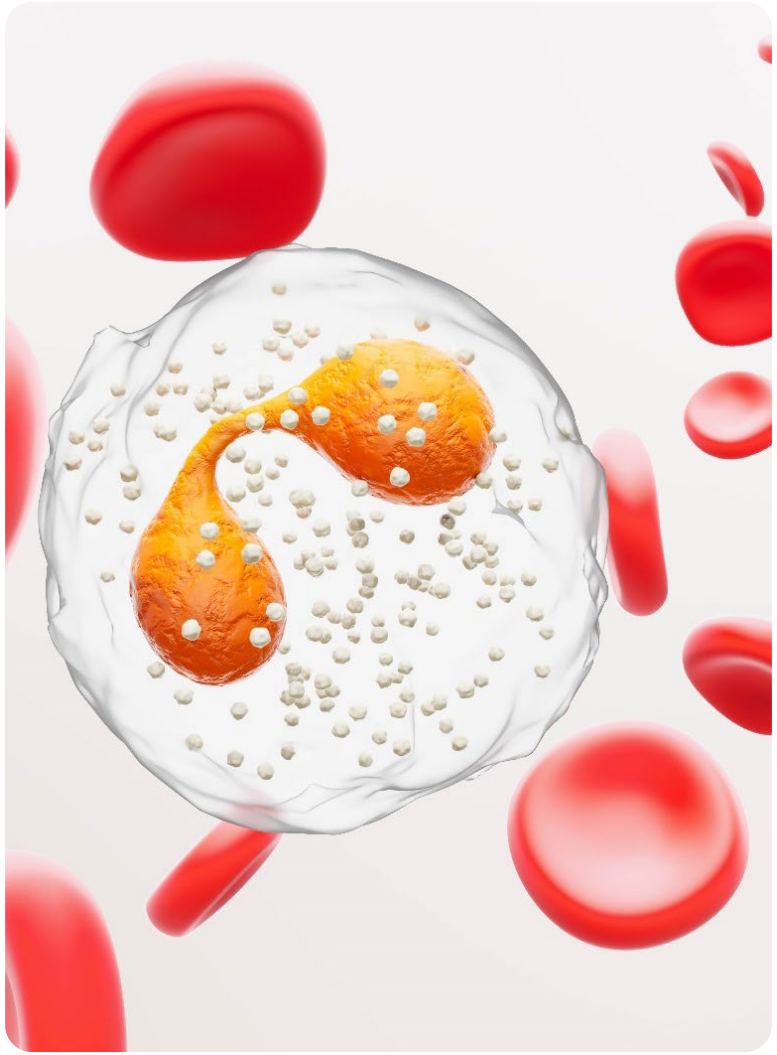
Agenda

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

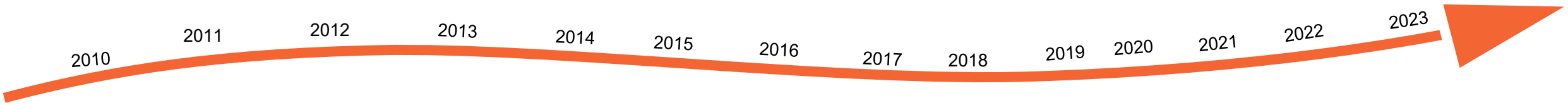
- *Shingrix* preferential approval put at risk and narrowly granted due to registered objections of insufficient minority representation in clinical studies
- Additional phase III study required for *Benlysta* to provide better representation among prevalent Black / African American women with Lupus

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



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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

GSK study on clinical trial diversity

Supporting industry efforts to improve representation in clinical trials

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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

Clinical trial diversity at ViiV Healthcare

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

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ViiV Healthcare's clinical trial diversity vision and mission

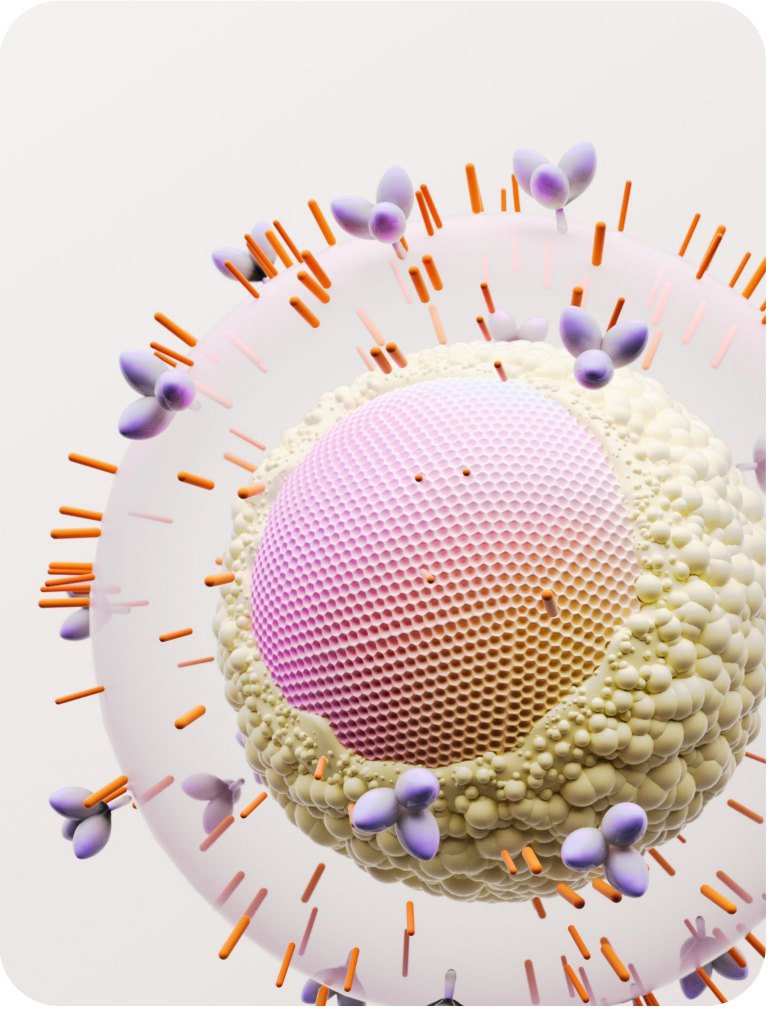
Vision

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



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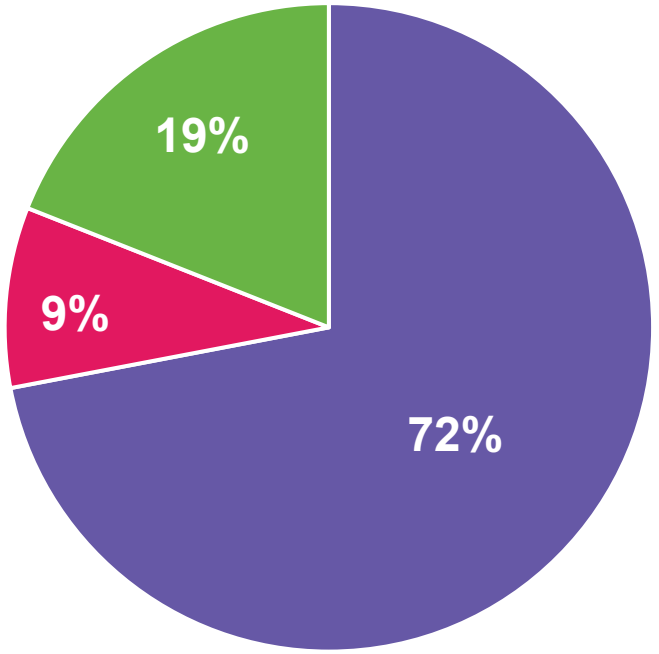
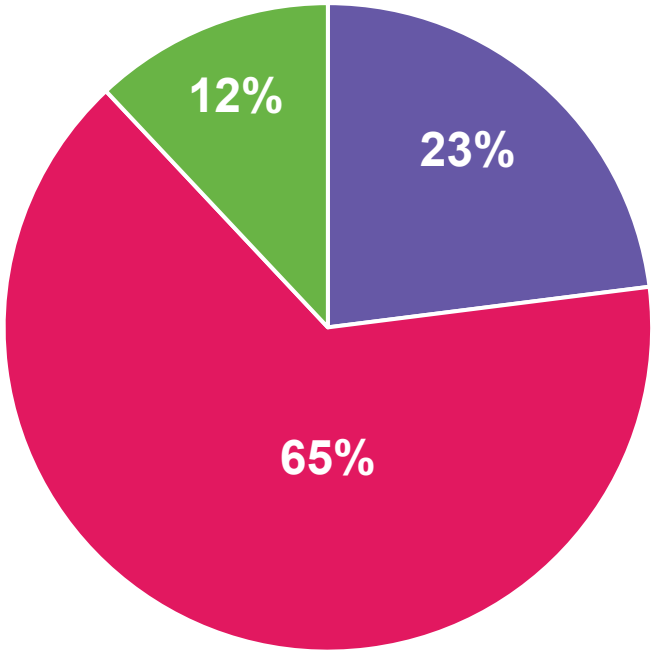
In HIV clinical trials, **Black individuals** are underrepresented relative to the overall global population of people with HIV

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

Estimated global population of people with HIV[1]



People with HIV in phase III HIV treatment RCTs[2] (N=19,055)[3]



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.

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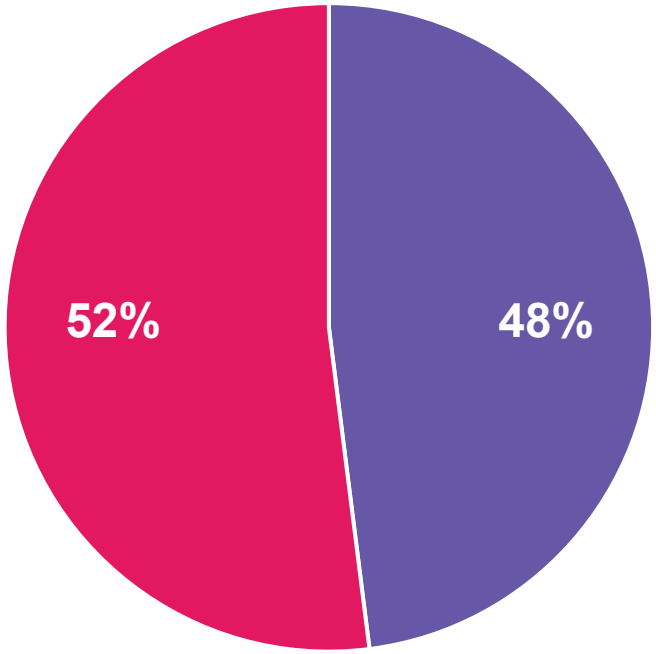
Evans and Dyson. 50th NBNA Annual Institute and Conference 2022; Chicago, IL. Slides.

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

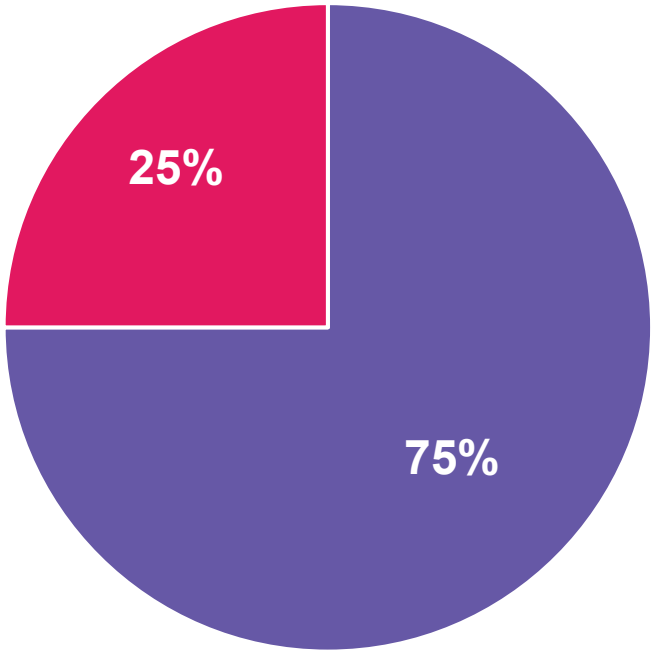
Estimated global population of people with HIV[1]



Male

Female

People with HIV in phase III HIV treatment RCTs[2] (N=19,055)[3]



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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.

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The global picture for HIV prevention

- Cabotegravir long acting (Cab LA): the first LA injectable for PrEP[1], 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 PrEP[1]
- HPTN 083: 4,570 cisgender MSM[2] and TGW[3] 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 enrolees in 083 were Black MSM[2], 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 year[4]
- **58%** of new infections are in sub-Saharan Africa [4]
- **63%** of new infections in sub-Saharan Africa are in young women and adolescent girls [4]
- ViiV signed a voluntary licence agreement with MPP[5] for Cab LA for PrEP[1] 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 but 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

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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.