



Sunnylands Retreat 2022: Ensuring Accessibility of Gene Therapy- Based Cures for HIV and Sickle Cell Disease

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The Annenberg Foundation Trust at
SUNNYLANDS

The Annenberg Trust at Sunnylands is an independent nonpartisan, nonprofit organization dedicated to convening global leaders in the public and private sectors to promote world peace, facilitate international agreement, and seek solutions to the most daunting challenges facing the world today.



Previous Sunnylands Retreats for HIV Cure

November 2013

*Summit on Public Private Partnerships for
Research Towards a Cure for HIV*

Objectives: To identify barriers to the rapid and coordinated expansion of HIV cure research, and to develop frameworks for novel collaborative networks to address key scientific questions emerging in the field

Results: \$100M commitment from the NIH for HIV cure research and a commitment by attendees to work collectively and aggressively towards developing a cure

February 2019

*Summit on the Path Towards
Ending HIV*

Objectives: To create a target product profile (TPP) for an HIV cure, specifically focused on a launch in sub-Saharan Africa, and to articulate the requirements for African healthcare systems to deliver a cure once available

Results: Establishment of the HIV Cure Africa Acceleration Partnership (HCAAP) and the publication of the TPP and a call to action for accelerating progress towards an HIV cure



HIV Cure Africa Acceleration Partnership (HCAAP) Achievements

Launch
HCAAP at
Georgetown

2019

2021

Publication
of TPP in
Lancet HIV

Publication
of HCAAP
call to
action in
Lancet HIV

2021

2022

Host Cure
Community
Education in
Uganda

Host
HIV/SCD
Retreat at
Sunnylands

2022



Collaboration between HIV and Sickle Cell Disease (SCD)

PUBLIC HEALTH

Gates and NIH join forces on HIV and sickle cell diseases

A unique marriage aims to speed development of simple DNA-based cures

By **Jon Cohen** and **Jocelyn Kaiser**

- Technical advancements in gene therapy are likely to lead to a cure for SCD in the near future.
- Like HIV, SCD disproportionally affects populations in sub-Saharan Africa.
- The regulations governing the production and commercialization of gene therapy as well as the delivery of the product will be the same regardless of the disease.
- Therefore, there are distinct benefits in collaboration between both the research and delivery communities working on HIV and SCD.



Sunnylands 2022: Ensuring Accessibility of Gene Therapy-Based Cures for HIV and Sickle Cell Disease

Hosts: HIV Cure Africa Acceleration Partnership in collaboration with the Annenberg Trust at Sunnylands

Goal: To develop specific, concrete plans to address critical barriers to the acceleration of the delivery of safe, effective, durable, and affordable “single-shot” gene therapy “cures” for SCD and HIV in sub-Saharan Africa.



Sunnylands 2022: Participants

- **Clinical/Research**

- Jennifer Adair
- Steve Deeks
- Cissy Kityo
- Sharon Lewin
- Julie Makani
- Thumbi Ndung'u
- Jamie O'Hara
- Helen Rees
- Gilmar Reis
- Alexis Thompson

- **Community**

- Moses Supercharger
- Elizabeth Merab

- **NGOs**

- CHAI (David Ripin)

- **Global Leadership**

- Africa CDC (John Nkengasong)
- WHO AFRO (Matshidiso Moeti)
- WHO (Rogerio Gaspar)

- **Funders**

- NIH (Carl Diffenbach)
- WH (Francis Collins)
- Aidsfonds (Mark Vermeulen)
- ANRS (François Dabis)
- FTX Foundation (Ross Rheingans-Yoo)
- BMGF (Mike McCune, Heather Ann Brauer, Julia Ginder)

- **Industry**

- Gilead (Jared Baeten)
- Caring Cross (Boro Dropulic)
- Greenlight Bioscience (Andrey Zarur)

- **HCAAP**

- Izukanji Sikazwe
- Mark Dybul
- Dominic Kemps
- Lauren Mathae
- Amy Lockwood

- **Sunnylands**

- David Lane
- Rob Fallon
- Kathleen Doherty





Sunnylands 2022: Discussion

01

STATE OF THE SCIENCE

What are the commonalities between gene therapies for HIV and sickle cell disease?

02

TARGET PRODUCT PROFILES

What might gene therapy cures for HIV and SCD look like?

03

DEVELOPMENT & DELIVERY

What do we need to do to bring these therapies to sub-Saharan Africa?

04

CLINICAL TRIAL INFRASTRUCTURE

What infrastructure investments are needed to ensure that sites in sub-Saharan Africa are prepared to conduct clinical trials?

05

REGULATORY PATHWAYS

How can efforts to govern and regulate cell and gene therapies in sub-Saharan Africa be accelerated?

06

COMMUNITY ENGAGEMENT

What activities need to be planned to engage with community and stakeholders to build support for gene therapy cures?

07

REIMAGING R&D AND COMMERCIALIZATION

How can we accelerate the introduction of gene therapy cures for HIV and SCD into sub-Saharan Africa?



Sunnylands 2022: Conclusion

- It's time to replace HCAAP, currently housed by Georgetown University and run from the US, with an organization that is defined by Africans and run by Africans.
- While this organization will be rooted in the initial concept of HCAAP, to advance cure for HIV and already embracing SCD, it will be expanded to address current and future pandemics and disease threats.
- The major stakeholders identified in the initial HCAAP charter will continue to be engaged, but this organization will broaden its remit to become a platform starting in basic science and discovery through to clinical delivery and patient uptake.



Sunnylands 2022: Working Groups

REGULATORY

There is a need to strengthen national regulatory processes in sub-Saharan African countries, perhaps through regional approaches. To do so, we should support the efforts of the African Medicines Agency (AMA), as well as the New Partnership for Africa's Development (NEPAD). Further, regulatory process and policies should not only be developed for gene therapy, but for all products.

STAKEHOLDER ENGAGEMENT

A stakeholder mapping and analysis is necessary in order to understand the groups with which to engage and their needs and priorities. This process will then guide the development of a strategy that outlines the formal role for each stakeholder group and a communications strategy to engage them in efforts to accelerating the launch of gene therapy cures for HIV and SCD in sub-Saharan Africa.

INVESTMENT & FUNDING

First a clear definition of what needs to be funded should be developed as different models lend themselves to different outcomes. Regardless, given the breadth of needs, there is a need to explore a variety of different sources for funding models from governments, to philanthropists, to corporations. However, the preference is for a sustainable model to aid the development of the originator pharmaceutical industry in sub-Saharan Africa to help build trade partnership and economic success.



Sunnylands 2022: Next Steps

HCAAP Project Continuation

- Publication in the Gene Therapy focused HIV Cure TPP
- Participation in the SCD TPP process, chaired by Novartis
- Cure Education Symposia in Zambia (and potentially Zimbabwe and South Africa)

Transition & Working Groups

- **Ongoing:** Meet with POCs at Africa CDC and WHO AFRO to discuss opportunity to transition leadership
- **August/September 2022:** Reconvene Sunnylands participants to discuss goals for each working group



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- Dominic Kemps
- Lauren Mathae
- Amy Lockwood

- **Bill & Melinda Gates Foundation**

- Mike McCune
- Julia Ginder

- **Global Leadership**

- John Nkengasong
- Matshidiso Moeti