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

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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 aggressive 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

- **2019**: Launch HCAAP at Georgetown
- **2020**: Publication of TPP in Lancet HIV
- **2021**: Publication of HCAAP call to action in Lancet HIV
- **2022**: Host HIV/SCD Retreat at Sunnylands
- **2022**: Host Cure Community Education in Uganda
Collaboration between HIV and Sickle Cell Disease (SCD)

- Technical advancements in gene therapy are likely to lead to a cure for SCD in the near future.

- Like HIV, SCD disproportionately 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

**STATE OF THE SCIENCE**
What are the commonalities between gene therapies for HIV and sickle cell disease?

**TARGET PRODUCT PROFILES**
What might gene therapy cures for HIV and SCD look like?

**DEVELOPMENT & DELIVERY**
What do we need to do to bring these therapies to sub-Saharan Africa?

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

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

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

**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.
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.

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.

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

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<th>HCAAP Project Continuation</th>
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<td>• Publication in the Gene Therapy focused HIV Cure TPP</td>
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<td>• Participation in the SCD TPP process, chaired by Novartis</td>
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<td>• Cure Education Symposia in Zambia (and potentially Zimbabwe and South Africa)</td>
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<th>Transition &amp; Working Groups</th>
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<td>• <strong>Ongoing</strong>: Meet with POCs at Africa CDC and WHO AFRO to discuss opportunity to transition leadership</td>
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<td>• <strong>August/September 2022</strong>: Reconvene Sunnylands participants to discuss goals for each working group</td>
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Acknowledgements

- The Annenberg Foundation Trust at Sunnylands
  - Rob Fallon
  - Kathleen Doherty
  - David Lane

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