



***Scientific Advancements in Gene Therapies:  
Opportunities for Global Regulatory Convergence***

*Hybrid Public Meeting*

*September 4, 2024*

*Reagan-Udall Foundation for the FDA  
1333 New Hampshire Ave, N.W., Rooftop Conference Room, Washington, DC*

- 10am**      **Welcome**  
Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA
- 10:05am**    **Opening Remarks**  
Peter Marks, MD, PhD, Center for Biologics Evaluation and Research, FDA  
Julie Makani, MD, PhD, Muhimbili University of Health and Allied Sciences(Tanzania), Tanzania High Commission to the UK  
Mike McCune, MD, PhD, Bill & Melinda Gates Foundation
- 10:20am**    **Session 1: The Current State of Gene Therapy**  
David Williams, MD, Harvard Medical School  
Eric Karikari-Boateng, MS, Food and Drugs Authority (Ghana)  
Kwasi Nyarko, PhD, WHO Regional Office for Africa (WHO-AFRO)  
Maneesha Inamdar, PhD, Institute for Stem Cell Science and Regenerative Medicine
- 11:35am**    **Session 2: Panel Discussion**  
Jimi Olaghere, Gene Therapy Recipient  
David Williams, MD, Harvard Medical School  
Eric Karikari-Boateng, MS, Food and Drugs Authority (Ghana)  
Kwasi Nyarko, PhD, WHO Regional Office for Africa (WHO-AFRO)  
Maneesha Inamdar, PhD, Institute for Stem Cell Science and Regenerative Medicine
- 12:15pm**    **Lunch break (lunch provided)**
- 1pm**        **Session 3: The Next Generation of Gene Therapies**  
David Liu, PhD, Broad Institute of MIT and Harvard  
Tony Ho, MD, Pivotal Lifesciences  
John Tisdale, MD, National Heart, Lung, and Blood Institute (NIH)  
Hildegard Büning, PhD, Hannover Medical School

- 2pm**            **10-minute break**
- 2:10pm**        **Session 4: Regulators' Perspective**  
Sol Ruiz, PhD, Spanish Medicines Agency (AEMPS)  
Peter Marks, MD, PhD, Center for Biologics Evaluation and Research, FDA  
Eric Karikari-Boateng, MS, Food and Drugs Authority (Ghana)
- 2:55pm**        **Session 5: How do we prepare for the next generation of gene therapy, as industry, regulators, and a health care system?**  
Hildegard Büning, PhD, Hannover Medical School  
Cecelia Calhoun, MD, MPHS, MBA, Yale University School of Medicine  
Jeremy Farrar, MD, PhD, World Health Organization  
Julie Makani, MD, PhD, Muhimbili University of Health and Allied Sciences (Tanzania), Tanzania High Commission to the UK  
Peter Marks, MD, PhD, Center for Biologics Evaluation and Research, FDA  
Kwasi Nyarko, PhD, WHO Regional Office for Africa (WHO-AFRO)  
Jimi Olaghere, Gene Therapy Recipient
- 3:55pm**        **Closing Remarks**
- 4pm**            **Adjourn**