

Framework for Initiating Pediatric Studies of HIV Cure Interventions: Scientific Knowledge Gaps, Regulatory and Ethical Considerations

NIAID Conference Center | 5601 Fishers Lane | Room 1D13

Rockville, MD 20852

May 22-23, 2018

Final Agenda

Day 1 Tuesday, May 22 8:30 AM – 5:00 PM Preliminary Session		
8:30 AM	Housekeeping Announcement and Introduction	Patrick Jean-Philippe, <i>National Institutes of Health</i> Veronica Miller, <i>The Forum for Collaborative Research</i>
8:35 AM	Welcoming Remarks	Sarah Read, <i>National Institutes of Health</i>
Session I: Setting the Stage - Scientific Background		
	Chairpersons:	Mark Cotton, <i>Stellenbosch University</i> Katherine Luzuriaga, <i>University of Massachusetts</i>
8:45 AM	Landscape of cure interventions and trials in adult populations	<i>Presenter:</i> Daniel Kuritzkes, <i>Harvard University</i>
9:00 AM	Landscape of cure interventions and trials in pediatric populations	<i>Presenter:</i> Deborah Persaud, <i>Johns Hopkins University</i>
9:15 AM	Immune system development in pediatrics	<i>Presenter:</i> Andrew Prendergast, <i>Queen Mary University of London</i>
9:30 AM	Age as a key parameter in anti-infective development: ontogeny informs precision medicine	<i>Presenter:</i> Ofar Levy, <i>Harvard Medical School</i>
9:45 AM	Unique aspects of pediatric immune responses in pediatric HIV cure	<i>Presenter:</i> Philip Goulder, <i>University of Oxford</i>
10:00 AM	Pediatric animal models - predictive ability	<i>Presenter:</i> Nancy Haigwood, <i>Oregon Health & Science University</i>
10:15 AM	Discussion	<i>Moderator:</i> Veronica Miller, <i>The Forum for Collaborative Research</i>
10:30 AM Break		
Session II: Product Development and Safety Consideration		
	Chairpersons:	Rohan Hazra, <i>National Institutes of Health</i> Paolo Palma, <i>Ospedale Pediatrico Bambino Gesù</i>
10:50 AM	Industry perspectives on HIV cure research in pediatric populations	<i>Presenter:</i> James Demarest, <i>ViiV Healthcare</i>
11:05 AM	Regulatory perspectives on pediatric HIV cure	<i>Presenter:</i> Yodit Belew, <i>U. S. Food and Drug Administration</i>
11:25 AM	Discussion	<i>Moderator:</i> Veronica Miller, <i>The Forum for Collaborative Research</i>
Session III: Ethical Considerations and Community Perspectives		
11:40 AM	Ethical perspectives on HIV cure research in pediatric populations	<i>Presenter:</i> Mariana Kruger, <i>Stellenbosch University</i>
	Community perspectives on HIV cure research in pediatric populations	
11:55 AM	Panel: Mutsa Bwakura-Dangarembizi, <i>University of Zimbabwe</i> Sandra Jones, <i>St. Jude Children's Research Hospital</i> Leslie Raneri, <i>Texas Children's Hospital</i> Maurice Williams, <i>Adolescent Medicine Trials Network</i>	<i>Moderator:</i> Veronica Miller, <i>The Forum for Collaborative Research</i>
12:20 PM	Discussion	<i>Moderator:</i> Veronica Miller, <i>The Forum for Collaborative Research</i>
12:35 PM	Convene Breakout Groups	Patrick Jean-Philippe, <i>National Institutes of Health</i>
12:40 PM Lunch		
Session IV: Breakout Group Deliberation		
1:40 PM	Breakout Groups Conference	
5:05 PM Day 1 - Adjourn		

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Day 2 Wednesday, May 23 8:30 AM – 12:20 PM Reports from Breakout Groups		
Session V: Upcoming pediatric trials of HIV cure interventions		
8:30 AM	<p><u>Study:</u> Prime Boost Therapeutic Vaccine Regimen +/- TLR4 agonist for HIV reservoirs in Children IMPACT Study P1115 IMPACT2008 Dual bNab Treatment in Children</p>	<p><u>Presenters:</u> Jintanat Ananworanich, <i>U.S. Military HIV Research Program</i> Ellen Chadwick, <i>Northwestern University</i> William Borkowsky, <i>New York University</i> Roger Shapiro, <i>Harvard University</i></p>
9:10 AM	Discussion	<p><u>Moderator:</u> Avy Violari, <i>The Perinatal HIV Research Unit</i> Theodore Ruel, <i>University of California, San Francisco</i></p>
Session VI: Breakout Groups Summary		
	Chairpersons:	<p>Philippa Musoke, <i>Makerere University</i> Sharon Nachman, <i>Stony Brook University</i></p>
9:30 AM	<p><u>Breakout Group 1 - Report</u> The pediatric patient: immunology and response to HIV <u>Lead Discussants:</u> Nigel Klein, <i>University College London</i> Yudit Belew, <i>U.S. Food and Drug Administration</i></p>	<p><u>Rapporteur:</u> Adriana Weinberg, <i>University of Colorado Denver</i></p>
9:45 AM	Questions and Comments	
9:50 AM	<p><u>Breakout Group 2 - Report</u> Approaches to pediatric studies I: Extrapolation of efficacy <u>Lead Discussants:</u> Ann Chahroudi, <i>Emory University</i> Prabha Viswanathan, <i>U.S. Food and Drug Administration</i></p>	<p><u>Rapporteur:</u> John Sleasman, <i>Duke University</i></p>
10:05 AM	Questions and Comments	
10:10 AM Coffee Break		
10:30 AM	<p><u>Breakout Group 3 - Report</u> Approaches to pediatric studies II: Prioritization of select interventions/strategies <u>Lead Discussants:</u> Elaine Abrams, <i>Columbia University</i> Kimberly Struble, <i>U.S. Food and Drug Administration</i></p>	<p><u>Rapporteur:</u> Louise Kuhn, <i>Columbia University</i></p>
10:45 AM	Questions and Comments	
10:50 AM	<p><u>Breakout Group 4 - Report</u> Ethical considerations and community perspective <u>Lead Discussants:</u> Steven Mphonda, <i>Supporting Operational AIDS Research (Project SOAR)</i> Liza Dawson, <i>National Institutes of Health</i></p>	<p><u>Rapporteur:</u> Anne Coletti, <i>FHI 360</i></p>
11:05 AM	Questions and Comments	
11:10 AM	<p><u>Breakout Group Panel Discussion</u> Nigel Klein, <i>University College London</i> Ann Chahroudi, <i>Emory University</i> Elaine Abrams, <i>Columbia University</i> Steven Mphonda, <i>Supporting Operational AIDS Research (Project SOAR)</i></p>	<p><u>Moderator:</u> Veronica Miller, <i>The Forum for Collaborative Research</i></p>
11:50 AM	Closing Remarks	<p>Patrick Jean-Philippe, <i>National Institutes of Health</i></p>
12:00 PM Workshop Adjourn		

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