

Consultation on the Inclusion of Adolescents in HIV Biomedical Prevention Clinical Trials

Doubletree Hotel
1515 Rhode Island Avenue NW, Washington DC 20005

June 17-19, 2009

AGENDA

June 17, 2009

4:00 - 6:30 p.m.
6:30 - 8:30 p.m.

Evening Arrival and Registration
Participant Dinner
Ceiba, 701 14th Street NW, Washington, DC 20005

June 18, 2009

8:00 - 9:00 a.m.

Breakfast and Registration

9:00 - 9:30 a.m.

Welcome and Introductions

Bill Kapogiannis

9:30 - 9:45 a.m.

Challenges with Adolescents and HIV Disease

Craig Wilson

9:45 - 10:00 a.m.

The HIV/AIDS Epidemic among Youth
Adolescent HIV medicine and research

Bret Rudy

10:00 - 10:15 a.m.

Adolescent Immunology

Paul Krogstad

10:15 - 10:30 a.m.

Adolescent behavioral considerations

Sybil Hosek

10:30 - 10:45 p.m.

Youth perspective

Gary Lawrence

10:45 - 11:00 a.m.

Discussion

11:00 - 11:15 a.m.

Break

11:15 - 11:30 a.m.

Biomedical Prevention Interventions

Michelle Lally

11:30 - 11:45 a.m.

The Context for Biomedical HIV Prevention with Young People

Glenda Gray

11:45 a.m. - 12:00 p.m.

HIV Vaccines

Ian McGowan

12:00 - 12:15 p.m.

Microbicides

Linda-Gail Bekker

12:15 - 12:30 p.m.

PrEP

Greg Zimet

12:30 - 12:45 p.m.

Risk reduction and disinhibition in prevention research

Discussion

12:45 - 1:30 p.m.

Lunch

1:30 - 1:50 p.m.

Drug Development Considerations

Bill Kapogiannis

1:50 - 2:10 p.m.

Adolescent Drug Development

Elizabeth Garner

2:10 - 2:30 p.m.

Lessons Learned from HPV vaccine Development in Adolescents

Skip Nelson

2:30 - 2:45 p.m.

Regulatory Considerations

Discussion

2:45 - 3:00 p.m.

Break

3:00 - 3:20 p.m.

HIV Prevention: Covering All of the Bases

Jon Ellen & Linda-Gail Bekker

3:20 - 3:40 p.m.

Community Engagement and Prevention Efforts

Kevin Fisher

3:40 - 4:00 p.m.

The Need for Advocacy

Becky Sheets

4:00 - 4:20 p.m.

Ethical, Legal, and Social/Cultural Barriers

Discussion

4:20 - 4:40 p.m.

Summary of Day One

Chuen-Yen Lau

4:40 - 5:00 p.m.

Overview of Presentations

Bill Kapogiannis

Description of Break Out Group Activity & Charge to the Groups

5:00 p.m.

Adjourn Day One

June 19, 2009

8:00 - 9:00 a.m.

Breakfast

9:00 - 9:15 a.m.

Introduction to and Instructions for Breakout Sessions

Bill Kapogiannis

9:15 - 10:15 a.m.

Breakout Sessions

Group 1: What data are needed to obtain adolescent indications for HIV biomedical prevention technologies?

Group 2: Behavioral and social concerns associated with the use of biomedical prevention technologies

Group 3: At what point in the research pipeline should adolescents be included in clinical trials?

10:15 - 10:30 p.m.

Break

10:30 - 11:00 a.m.

Rapporteur reports from the Breakout Sessions (10 min per group)

11:00 a.m. - 12:00 p.m.

Charting the Way Forward

Linda Lewis, Skip Nelson, Doug Pratt, Kimberly Struble

12:00 - 12:20 p.m.

Regulatory Agencies' Perspectives: Panel Discussion

The road to concurrent licensure

Discussion

12:20 - 12:30 p.m.

Concluding Remarks

B. Kapogiannis, C-Y Lau, & E. Handelsman

12:30 p.m.

Adjourn Day Two