



Pediatric Formulation of ARVs

Veronica Miller

www.hivforum.org

**Forum for Collaborative
HIV Research**

**School of Public Health &
Health Services**

**The George Washington
University**



The Forum for Collaborative HIV Research is a public/private partnership including government agencies, the pharmaceutical industry, HIV researchers and clinicians, and the HIV patient advocacy community.

Our mission is to facilitate and enhance HIV research.

**Forum for Collaborative
HIV Research**

**School of Public Health &
Health Services**

**The George Washington
University**

The Forum Executive Committee



- Government Agencies
 - US DHHS (NIH, CDC, FDA, HRSA, CMS), State Department (OGAC)
 - European Regulatory: EMEA
- Industries
 - Abbott, Bayer Diagnostic, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Roche Laboratories, Roche Molecular Systems, Pfizer-Agouron, Tibotec, Virologic
- Academia
 - US and Europe
- Providers
- Patient Advocacy
 - US and Europe
- Foundations & Organizations (Gates, IAS)

Steering Committee



David Burger - Radbound University Medical Centre Nijmegen

Ben Cheng - FCHR

Polly Clayden - HIV I-Base

Siobhan Crowley - WHO

Courtney Fletcher - University of Colorado

Di Gibb - Medical Research Council

Richard Hoetelmans - Tibotec

Veronica Miller - FCHR

Lynne Mofenson - NICHD

Siphokazi Mthati - Treatment Action Campaign

Jeff Safrit - Elizabeth Glaser Pediatric AIDS Foundation

Steve Spector - UC San Diego

**Forum for Collaborative
HIV Research**

**School of Public Health &
Health Services**

**The George Washington
University**

Agenda



9:00 - 9:15	Welcome and Introductions	Veronica Miller and John Gerber
9:15 - 9:30	Recommendations from the WHO meeting	Siobhan Crowley
9:30 - 9:45	Overview of issues regarding pediatric formulations	Di Gibb
9:45 - 10:00	Dosing/Formulations issues for pediatrics	Jennifer Kiser
10:00 - 10:20	Regulatory Perspective	Shabir Banoo, Ray Corrin, Kellie Reynolds, Nathalie Seigneuret
10:20 - 11:15	Industry Perspective	Abbott, Apotex, Bristol-Myers Squibb, Cipla, Gilead, GSK, Merck, Pfizer, Roche, Schering-Plough, Tibotec
11:15 - 11:30	Break	
11:30 - 12:30	Discussion	
12:30 - 13:30	Lunch in The Rose Room	
13:30 - 14:45	Discussion and developing a research agenda	
14:45 - 15:00	Next steps	Veronica Miller and John Gerber

**Forum for Collaborative
HIV Research**

**School of Public Health &
Health Services**

**The George Washington
University**

Meeting Objectives



- To identify the issues pertinent to pediatric formulations and treatment of HIV/AIDS in children
- To identify barriers to development of pediatric formulations
- To identify research questions that need to be addressed in order to develop guidelines and dosing regimen
- To identify the role of the various agencies and organizations in moving this field forward