



**Forum for Collaborative HIV Research
Standardization and Clinical Relevance of HIV
Drug Resistance**

**Workshop on Quantitative Methods for
Research of Antiviral Resistance
Boston, May 11-12, 2006**

**Forum for Collaborative
HIV Research**

**School of Public Health &
Health Services**

**The George Washington
University**

Special Thanks!



- Organizing Committee
- Workshop sponsors:
 - Vircolab, Bayer Diagnostic, GlaxoSmithKline
- Forum team:
 - Becky Griesse, Ipsita Das, Ben Cheng
- Meeting Masters:
 - Debbie Cooke and Cindy Harp



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

Our mission is to facilitate and enhance HIV research.

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The Forum Executive Committee



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

Standardization & Clinical Relevance of HIV Drug Resistance



- Need for a collaborative approach
- Standardized data analysis plan (www.hivforum.org)
- FDA, EMEA, all pharmaceutical/diagnostic industry, academic researchers and networks



Project Structure

- Chairs: D. Kuritzkes and V. Miller
- Sub-group planning committee chairs:
 - Genotypic algorithms: F. Brun-Vezinet and A. Zolopa
 - Phenotypic cut-offs: R. Haubrich and J. Eron
 - Technology and standardization: L. Demeter and R. Schuurman
 - Analysis: V. DeGruttola, D Costagliola and A N. Phillips



Project Planning Committee

- Government agencies: DAIDS, CMS, FDA (CDER & CBER), EMEA
- Organizations: WHO/IAS collaboration, IAS-USA
- Other initiatives: RDI, Stanford Database
- Industry – pharmaceutical
- Industry – diagnostic
- Research: virology, clinical, statistics, cost-effectiveness
- Patient community

Resistance Project – Phase I



- Standardized Analysis Plan (www.hivforum.org)
 - Written with input from all planning committee members
 - Encourage use of this standardized plan for analyses outside the Forum project
 - Encourage participation in a combined analysis
 - ACTG datasets
 - Industry datasets
 - Cohort Studies
 - others

Resistance Project (Costagliola, Cozzi-Lepri & Phillips)



- Phase I: existing and new algorithms for ddI and ABC response
 - Define responses (8 wk and 24 wk)
 - Comparison of current existing algorithms
 - Derivation of new algorithms
 - Based on logistic regression models
- Next steps: genotype and phenotype & response to boosted PIs
- Integration of genotype/phenotype information in clinical decision making

Costagliola et al 2005; Costagliola et al 2006*; Cozzi-Lepri et al 2006; Yang et al 2006

Resistance Project Phase II

DeGruttola et al



- Comparison of analytic approaches & methodologies