



Forum for Collaborative HIV Research
Center for Health Services Research and Policy
The George Washington University Medical Center

August 26, 2003

Dear Colleagues:

On behalf of the Forum for Collaborative HIV Research planning committee for the *Standardization and Clinical Relevance of HIV Drug Resistance Testing Project*, we are pleased to announce the publication of our data analysis plan and to invite you to be a collaborator in this project.

HIV-1 drug resistance is a significant factor for treatment failure and drug susceptibility testing is recommended by U.S. and European treatment guidelines, however, the interpretation of resistance test results remains a challenge. An urgent need for a more standardized interpretation of resistance test results in the clinical setting and in the drug development process has been identified. A standardized approach for a clinical database derived definition of drug resistance for each individual drug can be developed through collaboration across academia and industry.

In response to the need, the Forum for Collaborative HIV Research initiated the *Standardization and Clinical Relevance of HIV Drug Resistance Testing Project* in the autumn of 2001. The work of the international planning committee (see the Appendix to the Plan) and the various sub-committees has culminated in the collaborative data analysis project, described in the attached document, which was written by Andrew N Phillips, Dominique Costagliolia and Victor DeGruttola on behalf of the Data Analysis Writing Group.

This plan represents the first phase of this collaborative initiative and addresses the immediate pragmatic issues regarding differences in current interpretation systems. The group decided to begin with a pilot study looking at genotypic resistance patterns in association with response to didanosine and abacavir. Once this is underway, the project will be extended to look at other drugs. The Forum will continue to work on the longer term issues regarding a study of the methods used to derive interpretation systems. Such a comparative study of methodological approaches has not been undertaken before; thus it is likely that the work of this group will have an impact in fields outside of HIV.

There are two purposes to the publication of this plan: one is to facilitate the present collaborative effort, the other is to provide a standardized analysis plan for use by individuals or groups investigating drug resistance outside of this collaboration. The use of a standardized plan will aid in the interpretation of results and conclusions.

We are attaching the data analysis plan. For your convenience, this plan can also be downloaded from www.hivforum.org/xxxx. You will find additional information regarding this project at that site, including a report of the group's activities up to now and the groups that have provided financial support.

We hope that we have elicited your interest in joining this collaborative effort. We encourage research groups to send or otherwise make available datasets for a collaborative analysis coordinated by Andrew Phillips. If you would like to join, please contact Ben Cheng (bcheng@gwu.edu). Once we hear from you, we will provide you with a preferred format for data transfer. All resulting publications will be authored by the "working group", with an analysis and writing committee listed as an appendix, along with the investigators from the contributing groups.

If you prefer to use this standardized data analysis plan for individual analyses, or smaller group efforts, we welcome you to use the plan. We would appreciate it if you would inform us of any publications coming out.

We do look forward to hearing from you.

Yours sincerely,

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