Small Business Innovative Research Grants

• We have an announcement on the NIH website announcing our interest in funding the development of less expensive assays suitable for the developing world

• Website http://grants.nih.gov/grants/guide

• Or contact: Michael Ussery
  mussery@niaid.nih.gov 301-402-0134
Clinical Trials Networks

- DAIDS, NIAID, NIH funds a number of clinical trials networks (AACTG, PACTG, etc.) which have working groups that are engaged in transfer of laboratory technology and international training.
- Drs. Fiscus and Landay are a part of these efforts.
- Clinical trials that will show the utility of the methods proposed for the transfer of laboratory technology will likely be performed by these networks.
Virology Quality Assurance (VQA) Contract

• DAIDS funds a contract at Rush Medical Center in Chicago that is involved in the evaluation and quality assurance of virology assays.

• Evaluation of New Technologies:
  – Performance, Clade specificity
  – LOD, LOQ
  – Interday and intraday variability
• The VQA lab has just begun evaluations of the heat-denatured p24 assay (Perkin-Elmer) that has already been discussed by Dr. Fiscus
VQA-3

• Cavidi RT Assay (booth here at the meeting)
  – Very preliminary evaluations with Clade B have quantitated samples with viral loads of 750 copies/ml, but not 500 copies/ml
  – Clinical trials would need to be performed evaluating the utility of managing patients with such a cutoff
The VQA Laboratory also provides panels and manages proficiency testing and certification of NIH-funded international labs for measuring viral loads, genotyping, etc.

Ensures same high quality of data as in US clinical network studies
International Training Initiative

• Goal is to provide local/regional training to correct deficiencies found by our proficiency testing program

• We also use Fogarty Foundation programs to provide training for international laboratory personnel in U.S. laboratories.
Current Applicable SBIRs

- Norzyme: an enzymatic TDM test for PI much less expensive that currently available technologies. Currently undergoing clinical trials
- Genphar: an inexpensive method of phenotyping antiviral drug resistance for patient management which is currently under development