NEW YORK STATE DEPARTMENT OF HEALTH DIVISION OF EPIDEMIOLOGY BUREAU OF HIV/AIDS EPIDEMIOLOGY

REQUEST FOR INFORMATION (RFI)

I. PURPOSE OF RFI

The purpose of this RFI is to gather input from experts in the field of HIV drug resistance testing and analysis and from entities, whether corporate, academic or other, which currently perform analysis of HIV drug resistance information, to inform and support the procurement and/or development of an information system for the management and analysis of HIV drug resistance laboratory reports submitted to NYSDOH as mandated by regulation.

II. BACKGROUND

Under NYSDOH regulations implemented June 1, 2006, laboratories performing HIV drug resistance tests for all patients who are residents of New York State are required to submit the test results to NYSDOH. HIV drug resistance and subtype information is received by the Bureau of HIV/AIDS Epidemiology (BHAE). To accommodate an electronic reporting format and allow consistent analysis, the resistance data requested of laboratories is the viral genotype (reverse transcriptase and protease inhibitor nucleotide sequence).

Currently, laboratories submit results of resistance to NYSDOH electronically in the form of HIV protease and reverse transcriptase nucleic acid sequences. NYSDOH/BHAE estimates the volume of tests that will eventually be received from all laboratories to be on the order of 10,000-30,000 per year.

To use the incoming resistance information for purposes of HIV/AIDS surveillance and public health monitoring, BHAE needs a suite of specialized software tools for sophisticated, reliable and flexible data management and analysis. The systems will be used

- to identify otherwise unrecognized HIV cases for inclusion in the state's HIV/AIDS surveillance system
- to assess the prevalence and characteristics of drug resistance mutations among HIV/AIDS patients in New York State
- to scan for the occurrence of multiply drug resistant mutations that may pose
- to profile the frequency of HIV subtypes in New York's highly diverse population

Drug resistance monitoring data, like all data in the NYSDOH HIV/AIDS surveillance system, are to be used only in aggregate form. Data at the individual level are held confidential and are not released to any party outside NYSDOH, except for information supplied to the New York City Department of Health and Mental Hygiene, which conducts HIV/AIDS surveillance in the five boroughs (counties) of New York City, for routine case identification and to the Centers for Disease Control for purposes of national HIV/AIDS surveillance.

BHAE expects to contract with an appropriate vendor to supply an HIV drug resistance analysis software system to perform the following functions:

Required Software Functions

- 1) Maintain gene sequence data submitted by laboratories
- 2) Scan input sequences for data quality
- 3) Perform sequence alignment against standard HIV genotypes and identify viral subtype and mutations
- 4) Evaluate mutations to estimate viral resistance to antiretroviral drugs using explicit, recognized and publishable methods and standards
- 5) Output results to a resistance database at several levels of detail, including data on viral subtype and input data quality
- 6) Update analysis algorithms and sensitivity data appropriately
- 7) Link with existing BHAE data systems to the extent necessary for efficient data management

Because of data confidentiality and security requirements, the entire system – hardware, software, input data and output data – must reside within NYSDOH. Gene sequence data submitted by laboratories may not be transmitted outside NYSDOH.

The entire resistance analysis system will have to be delivered, installed and functional by the end of September, 2008.

III. INFORMATION REQUESTED

NYSDOH/BHAE is seeking to identify entities and organizations, whether commercial, academic, governmental or other not-for-profit, that currently perform HIV or other viral drug resistance analysis as described in the preceding section or have a similar capacity that could be adapted to our needs.

Specific kinds of information would include:

- Organization/entity name and contact information
- Description of the organization
- Brief description of drug resistance analysis capacity and achievements, with specific reference to HIV

NYSDOH/BHAE is NOT interested in learning about would-be suppliers, vendors or contractors who have not produced viral drug resistance analysis systems or lack relevant demonstrable bioinformatics qualifications and experience.

IV. RESPONSE DOCUMENTS

Responses should be written documents submitted on paper, via email or fax by October 15, 2007 to:

Daniel Gordon Bureau of HIV/AIDS Epidemiology Division of Epidemiology New York State Department of Health Corning Tower Albany, New York 12237

Fax: 518-474-5121

Email: deg02@health.state.ny.us

V. RESULTS

Information gathered from responses to this RFI may be used by NYSDOH to develop a request for proposals from potential vendors or suppliers for an HIV drug resistance analysis system.