HIV EAP Characteristics

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Washington, DC, 2009

- **Inclusion Criteria:**
- Patient cannot construct a viable regimen.
- Patients who are HIV sensitive to less than two active agents
- Patients who are intolerant of other regimens
- Permits use of other investigational drugs, including multiple investigational drugs
- Patients are eligible if there are no appropriate clinical trials available within a 50 mile radius or if the available clinical trials do not allow concomitant experimental drugs.

- EAP permits patients to use other investigational antiviral drugs.
- EAP maybe designed to specifically include two or more antiviral investigational drugs.
- Limited data collected: Demographics, viral load and CD4 counts, current regimens and safety data are the only data collected.
- Minimal forms and labor: Paperwork should be as simple as possible.
- Facilitates participation by private physicians, public and private clinics, as well as academic centers.
- Minimizes administrative burden on academic centers, private physicians, public and private clinics. Industry contributions support necessary EAP staff.
- National IRBs are available to provide convenient ethical oversight for private physicians, clinics and academic sites that do not require review from their own IRBs.

- EAP is available once a likely dose has been determined, sufficient drug-drug interaction and safety data are available for patients on a case by case basis and/or for intermediate sized patient groups of as many as 100 patients.
- EAP may be amended to include traditionally larger patient groups once more safety data or other relevant data are available or a separate larger can EAP can be also initiated.